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NEUROTOXINS AT HOME AND IN THE WORKPLACE

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HEARINGS

BEFORE THE

SUBCOMMITTEE ON
INVESTIGATIONS AND OVERSIGHT

OF THE

COMMITTEE ON
SCIENCE AND TECHNOLOGY
HOUSE OF REPRESENTATIVES

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NEUROTOXINS AT HOME AND IN THE WORKPLACE

TUESDAY, OCTOBER 8, 1985

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:06 a.m., in room 2325, Rayburn House Office Building, Hon. Harold L. Volkmer (chairman of the subcommittee) presiding.

Mr. VOLKMER. The Subcommittee on Investigations and Oversight will come to order.

Today we will begin hearings on neurotoxins. Chemicals are an everyday fact of life in modern society. They enhance our lives in ways too numerous to count, but progress has its price, and too often the price of the role of chemicals in our society is human illness and disease.

In recent years we have made great progress in protecting the public from chemicals that cause cancer, but there are dangers other than cancer. Nerve poisons, called neurotoxins, are one of the leading causes of illness in the workplace. Daily exposure to neurotoxins can cause subtle disorders of the mind and body that cause accidents and injuries. These subtle defects, if undetected and untreated, can lead to irreversible disabling disorders that affect every aspect of the victim's life.

Neurotoxins are not just an industrial problem. They can be in our children's paint, our perfumes, our food, and our medications. We need the best research available to make sure that these products work for us, not against us.

Today this subcommittee will hear testimony about the most recent discoveries regarding the health effects of neurotoxins. We will hear firsthand how exposure to neurotoxins has affected one man's life.

We will also hear today from some of the leaders in the field how we might test new and existing chemicals for neurotoxic effects before we expose workers or the public.

Tomorrow we will focus on neurotoxins in the workplace. OSHA, the agency charged with protecting workers from significant health risks, has done relatively little in the last 14 years to incorporate the research on neurotoxins and workplace health standards. OSHA's reasons for ignoring the latest research regarding neurotoxins will be of special interest to the subcommittee.

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Finally, we will examine what is being done to warn workers of chemical dangers they face and what technology is available to monitor the safety of the workplace and the health of our workers.

We hope these hearings will help us to understand and solve the problems caused by neurotoxins. We intend to bring to light the major research progress our scientists have made in this area and discuss how that progress can help us to make our world a safer place.

I would now like to ask the first panel to be seated, but before we go to that, I would first recognize the gentleman from California, Mr. Packard, for an opening statement.

Mr. PACKARD. Thank you, Mr. Chairman.

I'm pleased that we have called these hearings because it is time that we do examine the dangers of some of the substances posed to the human nervous system.

As a dentist, I'm aware of some of the substances I used in my dental work which were, in fact, potentially dangerous to both my health and the health of my patients.

There are substances commonly used in the home that make our lives easier. We use these substances in good faith, seldom questioning the fact that they could cause peripheral nerve or brain damage. Consumers rely on the Government's and industries' judgment on health dangers associated with the use of chemicals and pesticides.

While there is concern about the use of some of these substances, there are more serious concerns about the workers who spend 8 hours a day in making these substances.

I look forward to hearing today's witnesses and trust that they will discuss the extent of the neurotoxic exposure.

Further, I want to hear opinions on how adequately our Federal agencies charged with the responsibility for testing the safety of chemicals, pesticides, and additives are testing substances for their neurotoxic effects.

Thank you very much, Mr. Chairman, for calling the hearings. I look forward to each of the witness' testimony.

Mr. VOLKMER. Our first panel will consist of Dr. Bernard Weiss, University of Rochester Medical Center—Dr. Weiss, will you please come up to the table; Dr. Peter Spencer from the Albert Einstein College of Medicine in New York; and Mr. Frank Carsner, a painter from Portland, OR.

We'll begin with Dr. Weiss.

And, Doctor, and all the witnesses, if you have a prepared statement, that statement will be made a part of the record in full, and you may either review the statement in full or summarize, however you so desire.

STATEMENT OF DR. BERNARD WEISS, DIVISION OF TOXICOLOGY, UNIVERSITY OF ROCHESTER MEDICAL CENTER, ROCHESTER, NY

Dr. WEISS. I will summarize the statement.

Mr. Chairman, Mr. Packard, ladies, and gentlemen, these hearings testify to the growing maturity of the scientific disciplines of behavioral and neurotoxicology.

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Not too long ago we viewed the threat of death or serious illness as the main basis on which to control and regulate exposure. Now we also worry about subtle and insidious toxicity expressed mainly as impaired function.

Behavioral assessments emerged as a guide to such effects because a person's behavior reflects subtle disorders of mood and movement, of intellectual keenness and emotional stability, of subjective state and objective performance.

People, after all, do not complain of altered levels of brain enzymes or the loss of nerve cells. They complain of feeling irritable or notice lapses of memory.

Toxic chemicals are not a new problem. Heavy metals such as mercury and lead have been recognized since antiquity as nervous system poisons. The vapors of metallic mercury, the kind used in thermometers, produce an intriguing collection of symptoms that go by the name of erethism. It includes hyperirritability, blushing, labile temperment, timidity, depression, fatigue, insomnia, and the avoidance of public places. Mercury also induces tremor.

Metallic mercury is treacherous because erethism can be mistaken for a response to circumstances such as marital difficulties. One victim, a woman exposed to mercury in a factory near Rochester, complained to one physician after another that she was not herself. Without asking about her occupation, they prescribed tranquilizers.

Another form of mercury, methylmercury, is found at high levels in certain species of marine fish and in fish from lakes and rivers contaminated by mercury. Contaminated seafood in Minamata, Japan caused many deaths and widespread neurological impairment, beginning in the 1950's, among the local fishermen and their families.

More recently, in the winter of 1971–72, an epidemic of methylmercury poisoning struck Iraq, causing about 5,000 deaths and rampant nervous system injury. The methylmercury came from seed grain treated with a methylmercury fungicide. The aftermath of that exposure confirmed the suspicion that the fetal brain was far more vulnerable to methylmercury damage than the adult brain. Children whose mothers consumed the tainted grain during pregnancy suffered developmental disabilities such as retarded speech acquisition.

The episodes in Minamata and Iraq stimulated a large volume of research in what is now called Behavioral Teratology. Teratologies are birth defects, and the adjective "behavioral" acknowledges that functional consequences are as much defects as are gross deformities.

Lead is another of the ancient metals. Overt lead poisoning used to be common in the lead industries. Now we recognize that clinical lead poisoning is only the culmination of a process that begins with subtle functional deficits.

Most of the publicity about lead, however, stems from evidence that even mild to moderate exposures may damage the developing brain. Dr. Herbert Needleman and his collaborators published a landmark study in 1978 based on the analysis of lead in baby teeth from over 2,000 first and second graders in two Boston suburbs. The study revealed differences in IQ scores and psychological test performance between the children with the highest and the lowest

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teeth levels. None of these children would have been considered poisoned on the basis of blood lead concentrations.

The data from Boston have since been confirmed by other studies in other countries. They tend to show a difference in IQ scores of about 5 points between children exposed to low levels and children exposed to moderate levels of lead. Let me convey the significance of that seemingly small difference by the following argument:

Intelligence tests are designed so that the average score is 100. In a population of 100 million, 2.3 million individuals will score above 130, the kind of intelligence you need to produce weapons and science like this. If the average falls to 95, only 990,000 individuals will score above 130. In this technologically competitive world such an outcome is a societal disaster.

A major class of workplace chemicals is the volatile organic solvents. It includes substances such as carbon disulfide, used in rayon production; perchlorethylene, used in dry cleaning; trichlorethylene, used in degreasing; and many others. The general public is exposed in glues and paint thinners, in household cleaners. Industrial exposure standards for these chemicals are set partly on the basis of their acute anesthetic effects.

A new kind of argument has erupted during the last few years, however. Its source is the claim, advanced most insistently by Scandanavian investigators, that chronic exposure to solvents induces a characteristic group of signs and symptoms now identified as the Organic Solvent Syndrome. It is distinguished by evidence of neurological damage accompanied by a gamut of psychological complaints and by flawed performance on various psychological tests. The gravest defect in this literature is the absence of an animal model, based on extended chronic studies.

Such chronic studies, incorporating advanced behavioral assessment techniques, might also lead to new questions. For example, Dr. William Merigan at Rochester assayed the subchronic effects of the chemical acrylamide on visual system function in trained monkeys. Although other aspects of visual performance recovered after dosing ended, visual acuity, measured by advanced methods, remained impaired. This work emphasizes the need to apply advanced assessment techniques for detecting early, subtle damage. The typical clinical neurological examination is aimed at the detection of frank disease, not its equivocal and often reversible precursors.

Equivalent comments pertain to insecticides. Many of these chemicals are designed specifically to poison the nervous systems of insect pests, so it comes as no surprise that they also can poison the human nervous system. One class of insecticides, the organophosphates, is related chemically to potent war gases.

Workers at a plant in Texas displayed symptoms such as anxiety, impaired memory, and confusion, and several neurological signs. The diagnostic ambiguity led NIOSH investigators to recommend monitoring exposed workers with psychological tests. The earliest effects of another insecticide, distantly related to DDT, were described as nervousness. How many plant physicians do you suppose would suspect a toxic chemical as the reason rather than, say, family problems?

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Even food additives have been implicated in behavioral toxicity. The late Ben F. Feingold asserted that many of the children labeled as hyperactive actually were the victims of an elevated sensitivity to certain constituents of the diet, particularly synthetic food colors and flavors. Controlled trials of the hypothesis have, indeed, confirmed that some children respond with disturbed behavior to food colors and that some children benefit from a diet free of additives. Such data indicate that food additives should be tested for behavioral toxicity because the synthetic color levels permitted in human diets are about 50 times greater than those arousing behavioral reactions in susceptible children.

Before I end my statement, I would like you to consider one further set of implications. Nervous system dysfunction during advanced age seems destined to become the dominant disease entity of the 21st century. Neither I, nor anyone else, can tell you how much of that dysfunction might be attributable to toxic chemicals in the environment.

Thank you.

[The prepared statement of Dr. Weiss follows:]

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STATEMENT OF DR. BERNARD WEISS

Professor of Toxicology and
Deputy Director, Environmental Health Sciences Center
University of Rochester School of Medicine and Dentistry

Mr. Chairman, members of Congress, ladies and gentlemen. These hearings testify to the growing maturity of the scientific disciplines of behavioral and neurotoxicology. It is a status won by an enlarged public awareness of how to judge the hazards of potentially toxic chemicals. Not too long ago, we viewed the threat of death or serious illness as the main basis on which to control and regulate exposure. Now, we also worry about subtle and insidious toxicity expressed mainly as impaired function.

Behavioral assessments emerged as a guide to such effects because a person's behavior reflects subtle disorders of mood and movement, of intellectual keeness and emotional stability, of subjective state and objective performance. People, after all, do not complain of altered levels of brain enzymes or the loss of nerve cells. They complain of feeling irritable, or notice lapses of memory--phenomena that the science of Psychology, with over a hundred years of experience, has learned how to measure.

Toxic chemicals are not a new problem. Heavy metals such as mercury and lead have been recognized since antiquity as nervous system poisons. They produce signs and symptoms ranging from subjective complaints such as depression to overt disabilities such as loss of coordination. During the last century, manganese was also recognized as neurotoxic. Workers, such as miners, who inhale manganese dust or fumes develop a syndrome marked both by a neurological disorder partially resembling Parkinson's Disease, and by a cluster of behavioral disturbances. Miners in South America call the cluster, "locura manganica," or manganese madness.

The vapors of metallic mercury, the kind used in thermometers, produce an intriguing collection of symptoms that goes by the name of erethism. It

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includes hyperirritability, blushing, labile temperment, timidity, depression, fatigue, insomnia, and the avoidance of public places. Mercury also induces tremor severe enough in some victims to be disabling. Despite the long history of mecurialism, only within about the last 15 years have sensitive measurement techniques been applied to study its features in workers. These have demonstrated psychological and neurological dysfunction at mercury levels in the blood that earlier had been thought free of adverse effects. Metallic mercury is uniquely hazardous among metals because it evaporates readily and, when inhaled, accumulates in the brain. It is treacherous, too, because erethism can be mistaken for a response to circumstances such as marital difficulties. One victim, a woman exposed to mercury in a factory near Rochester, complained to one physician after another that she "was not herself." Without asking about her occupation, they prescribed tranquilizers. She diagnosed her own affliction before coming to the University of Rochester Medical Center. Mercury vapor toxicity seems mostly reversible, however, and there is little evidence that it kills nerve cells.

Another form of mercury is significant on a more global ecological scale. Methylmercury is found at high levels in certain species of marine fish and in fish from lakes and rivers contaminated by mercury. Methylmercury is an even more potent nervous system poison than mercury vapor and kills brain tissue. Contaminated seafood in Minamata, Japan, traced eventually to the effluent from a factory, caused many deaths and widespread neurological impairment, beginning in the 1950s, among the local fishermen and their families. More recently, in the winter of 1971-1972, an epidemic of methylmercury poisoning struck Iraq, causing about 5,000 deaths and rampant nervous system injury. The methylmercury came from seed grain treated with a methylmercury fungicide

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applied at the request of the Iraqi government. Peasant families baked the seed grain into bread rather than planting it. The aftermath of that exposure, investigated by Rochester faculty and their Iraqi collaborators, confirmed the earlier suspicion, provoked in Minamata, that the fetal brain was far more vulnerable to methylmercury damage than the adult brain. Children whose mothers consumed the tainted grain during pregnancy suffered developmental disabilities such as retarded speech acquisition. The episodes in Minamata and Iraq stimulated a large volume of research in what is now called Behavioral Teratology. Teratologies are birth defects, and the adjective, behavioral, acknowledges that functional consequences are as much defects as are gross deformities. Methylmercury may be an emerging problem in this country because it is elevated in fish from acidified lakes.

Lead is another of the ancient metals. Some authorities believe that it played a significant role in the dissolution of the Roman Empire because the Roman aristocracy consumed huge amounts of lead. They stored their wine in leaden casks, added lead compounds to preserves, and, according to these observers, gradually poisoned themselves out of power. Overt lead poisoning used to be common in the lead industries. Now, because of the volume of research on lead-exposed workers, we recognize that clinical lead poisoning is only the culmination of a process that begins with subtle functional deficits. As a result, the acceptable exposure standards for industry gradually have fallen.

Most of the publicity about lead, however, stems from evidence that even mild to moderate exposures may damage the developing brain. A pioneer in the current research scene, Dr. Herbert Needleman, now at the University of Pittsburgh, and his collaborators published a landmark study in 1979. It was

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based on the analysis of baby teeth from over 2,000 first and second graders in two Boston suburbs. Dr. Needleman and his colleagues analyzed baby teeth for lead because teeth, like bones, accumulate lead, and so provide a history of lead exposure. Lead in blood reflects only recent exposure. The Needleman study revealed differences in I.Q. scores and psychological test performance between the children with the highest and the lowest teeth levels. These levels were also correlated with teacher ratings of classroom behavior. None of these children would have been considered poisoned on the basis of blood lead concentrations. Further data from this research group indicate that even lower exposure levels than these, if experienced during fetal development, may impair behavioral function.

The data from Boston have since been confirmed by other studies in other countries. They tend to show a difference in I.Q. scores of about five points between children exposed to low levels and children exposed to moderate levels of lead. Let me convey the significance of that seemingly small difference by the following argument. Intelligence tests are designed so that the average score is 100. In a population of 100 million, 2.3 million individuals will score above 130. If the average falls to 95, only 990 thousand individuals will score above 130. In this technologically competitive world such an outcome is societal disaster. It reminds me of a question once put by Dr. David Rall, Director of the National Institute of Environmental Health Sciences. Suppose, he asked, that the drug thalidomide, instead of producing missing limbs and other deformities, had lowered the average I.Q. of the affected children by 10 percent. Would we, even now, suspect any adverse effects of the drug? The obvious answer pervades this emerging science.

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A major class of workplace chemicals is the volatile organic solvents. It includes substances such as carbon disulfide, used in rayon production; perchlorethylene, used in dry cleaning; trichlorethylene, used in degreasing; and many others. The general public is exposed to such substances in glues, in paint thinners, in household cleaners. Industrial exposure standards for these chemicals are set partly on the basis of their acute anesthetic effects and the dangers these pose to plant and worker safety. A new kind of argument has erupted during the last few years, however. Its source is the claim, advanced most insistently by Scandanavian investigators, that chronic exposure to solvents, like that experienced by painters and other workers, induces a characteristic group of signs and symptoms now identified as the Organic Solvent Syndrome. It is distinguished by evidence of neurological damage ranging from brain atrophy to impaired balance to slowed electrical responses in the nervous system. These signs are accompanied by a gamut of psychological complaints and by flawed performance on various psychological tests. Although much of the earlier Scandanavian research has been criticized for defects in design and execution, the more recent work is less vulnerable to criticism and still upholds the basic hypothesis. The gravest defect in this literature is the absence of an adequate laboratory animal model, a defect that stems largely from the reluctance of both investigators and their sources of research support to undertake extended chronic studies.

Such chronic studies, incorporating advanced behavioral assessment techniques, might also lead to new questions. For example, Dr. William Merigan, at Rochester, assayed the subchronic effects of the chemical acrylamide on visual system function in trained monkeys. Acrylamide, although not a solvent, induces a form of nerve damage resembling that induced by

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certain solvents. Common laboratory animals such as rats and mice were not suitable for this experiment because their visual system structure and function differ so markedly from that of humans. Dr. Merigan discovered that, although other aspects of visual performance recovered after dosing ended, visual acuity, measured by advanced methods, remained impaired. That finding led him and our neuropathologist collaborators to the further discovery that the enduring impairment arose from destruction of a certain class of cells in the retina of the eye. This work emphasizes the need to apply advanced assessment techniques for detecting early, subtle damage. The typical clinical neurological examination is aimed at the detection of frank disease, not its equivocal and often reversible precursors.

Equivalent comments pertain to insecticides. Many of these chemicals are designed specifically to poison the nervous systems of insect pests, so it comes as no surprise that they also can poison the human nervous system. One class of insecticides, the organophosphates, is related chemically to potent war gases, and is responsible for many deaths annually, mostly in the less developed countries. Overt organophosphate poisoning is fairly easy to recognize, but the syndrome induced by low-level chronic exposure is far less salient. Workers at a plant in Texas, exposed in the process of manufacturing such an insecticide, displayed symptoms such as anxiety, impaired memory, and confusion, and several neurological signs. The diagnostic ambiguity before their source finally was identified led NIOSH investigators to recommend monitoring exposed workers with psychological tests. The earliest effects of another insecticide, distantly related by chemical class to DDT, were described as nervousness. How many plant physicians do you suppose would suspect a toxic chemical as the reason rather than, say, family problems?

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Even food additives have been implicated in behavioral toxicity. The late Ben F. Feingold, a pioneer in pediatric allergy, published a book in 1975 asserting that many of the children labelled as hyperactive actually were the victims of an elevated sensitivity to certain constituents of the diet, particularly synthetic food colors and flavors. He focused on colors and flavors because they lacked any nutritional value and typically were added to help market what often are called junk foods. This novel claim was at first derided, but subsequent controlled trials of the hypothesis have indeed confirmed that some children respond with disturbed behavior to food colors and that some children benefit from a diet free of additives. Moreover, the experiments suggest that the youngest children respond most readily, an outcome that would not surprise anyone familiar with behavioral teratology. Such data indicate that food additives should be tested for behavioral toxicity as well as for carcinogenic potential, because the synthetic color levels permitted in human diets on the basis of traditional toxicity testing are about 50 times greater than those arousing behavioral reactions in susceptible children.

This brief survey was meant only to acquaint you with the background of current efforts in behavioral and neurotoxicology. Before I end my testimony, however, I would like you to consider one further set of implications. Nervous system dysfunction during advanced age seems destined to become the dominant disease entity of the twenty-first century. Neither I, nor anyone else, can tell you how much of that dysfunction might be attributable to toxic chemicals in the environment. So far, hardly anyone has looked. Thank you.

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Mr. VOLKMER. Thank you very much, Dr. Weiss.
We will now hear from Dr. Peter Spencer.

STATEMENT OF DR. PETER S. SPENCER, DIRECTOR, INSTITUTE OF NEUROTOXICOLOGY, ALBERT EINSTEIN COLLEGE OF MEDICINE, BRONX, NY

Dr. SPENCER. Mr. Chairman, Mr. Packard, I have a 10-minute statement, if I could take the first paragraph as read.

I introduce the subject of my discussion with two principles, both of which are clearly established and widely accepted.

The first is that the nervous system has an enormous biological responsibility in directing and maintaining normal bodily functions and in processing, storing, and releasing information that allows the human being to be unique among mammals. It allows us to think, remember, recall, to have emotion and personality, to act rationally and responsibly, to sleep and to wake, to walk and to run, to see, smell, taste, hear, and to sense touch and pain. All of this—and much more—is possible because of the exquisite structural and functional coordination of special cells found in the brain, spinal cord, and nerves that supply vital organs, skin, and muscle.

The second principle is the nervous system is commonly affected by chemical substances present in the environment. Some of these effects are short-lasting and reversible: the inebriated state that follows excessive intake of an alcoholic beverage is familiar to one and all.

Other effects of environmental chemicals are long-lasting, permanent, and sometimes even progressive. Such changes may occur with single or repeated chemical insult to the nervous system: an example of the latter is the chronic alcoholic who suffers mental deterioration, psychosis and hallucination, et cetera, et cetera.

Chronic neurotoxic diseases are almost always associated with structural breakdown of parts of the nervous system, although prolonged imbalance of critical chemical systems used by the brain to transmit information can also precipitate chronic, debilitating neurological dysfunction. The periodic or relentless involuntary movements of the schizophrenic or Parkinsonian patient on chronic drug therapy provide graphic examples of the disastrous effects of chronic chemical imbalance in the brain.

It will be apparent from these two principles that we are all at risk for neurotoxicity, that the effects are often cumulative, and that they may result in devastating neurological or psychiatric disorders that impair the quality of life, cripple, and potentially reduce the highest intellect to a vegetative state.

Those at greatest risk include the unborn or newborn child whose brain is inadequately shielded from toxic substances in the blood; the drug abuser who is repeatedly exposed to large concentrations of neurochemically-active substances; the undernourished whose nervous system may already be compromised by nutritional insufficiency; the worker who has a lifetime exposure via skin and lungs to potential neurotoxins; and the aged whose nervous system—already impaired by the aging process and by a lifetime of polypharmacy and environmental chemical exposure—is more susceptible to the effects of chemical attack.

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I would like to offer some recent examples of chemicals with chronic neurotoxic potential. They include substances in the workplace, in the home, in the general environment, in food, cosmetics, and in self-prescribed medicines.

My first example may be somewhat surprising. It is a required vitamin. Vitamin B6 is freely available in health food stores in tablets as large as 1 gram. Repeated use of one-quarter of that dose to ameliorate the premenstrual syndrome has caused walking defects in young women mistakenly diagnosed as having multiple sclerosis. Similar problems have occurred among weight lifters and those persuaded of the "merits" of megavitamin therapy.

We learn from this experience that the nervous system cannot tolerate repeated exposure to abnormal levels of certain chemical substances, even if they are natural materials and actually required for normal neurological and body function. B6 megavitamin neurotoxicity could have been avoided, however, if we had heeded the toxicology literature where this phenomenon was clearly demonstrated in experimental rodent studies.

The second example concerns two synthetic chemicals that were generally regarded as safe as artificial flavoring additives and widely employed as synthetic musks in soaps, creams, perfumes, after-shave lotions, and detergents. In 1955, AETT was introduced into fragrance preparations without testing for chronic toxicity and in 1977-78 voluntarily withdrawn by the fragrance industry after repeated exposure to the unbroken skin of rats had demonstrated degeneration of brain neurons and structural changes in spinal cord and in nerves supplying the limbs.

An unusual early sign was increased irritability, a behavioral change I remember well because the rats had a tendency to bite. We may never know whether humans reacted similarly to Musk AETT, although the prospect of a widely used fragrance chemical that penetrates human skin and induces aggressive tendencies by damaging the brain leaves much to the imagination.

The second neurotoxic fragrance compound, Musk Ambrette, introduced in the 1920's, used in quantities exceeding 100,000 pounds per year for over 50 years, and has yet to be removed from the marketplace. Hundreds of other compounds used in fragrance formulations remain to be tested for chronic neurobehavioral toxicity.

I'll skip the next paragraph, if I may.

Workplace exposure to—but I'd like you to include it—workplace exposure to chemicals is a frequent cause of serious neurotoxic disease: lost sensation from acrylamide, partial paralysis from n-hexane; tremor and abnormal eye movements from Kepone, inability to urinate from DMAPN, and, most recently, the constellation of neurological abnormalities induced by a compound BHMH.

This was introduced in 1979 as a catalyst in the manufacture of reinforced bathtubs. After only a few weeks of use at a plant in Lancaster, TX, several exposed workers experienced dizziness, pins-and-needles, muscle weakness, incontinence, memory loss, and disturbed vision. Some of those affected still displayed weakness and sensory loss 2 years later. The epidemic could have been prevented by adequate premarket evaluation of BHMH because appropriate animal studies conducted after the epidemic demonstrated a com-

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parable disease in rats repeatedly exposed to the compound via their skin. No such testing was required or performed.

In summary, chemical substances with neurotoxic potential are legion. The majority of neurotoxic disease probably results from the side effects of therapeutic and abused drugs, including alcohol, although numerous examples of environmental epidemics, industrial accidents, and ill-advised consumption of purified chemicals have caused large numbers of individuals to develop overt neurological deficits. These probably represent the tip of the iceberg since more subtle neurotoxic changes go unrecognized.

We are ignorant of the long-term effects of substances with neurotoxic potential added to food, present in skin care products, or used in the workplace.

Finally, of the 588 chemicals for which occupational standards are set by the American Conference of Governmental Industrial Hygienists, 167, approximately a quarter, have direct nervous system effects as a basis of their regulation. Many more will be discovered if we subject the inventory of chemical substances to experimental testing for neurotoxicity.

Thank you.

[The prepared statement of Dr. Spencer follows:]

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U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE AND TECHNOLOGY
SUB-COMMITTEE ON INVESTIGATIONS AND OVERSIGHT

HEARING ON NEUROTOXINS
OCTOBER 8-9, 1985

October 8 Morning Testimony of Peter S. Spencer, Ph.D., M.R.C.Path.

WHERE NEUROTOXINS OCCUR AND WHAT THEY DO

My name is Peter S. Spencer, and I am a U.S. citizen residing in New York State. My professional affiliation is with the Albert Einstein College of Medicine where I am Professor of Neuroscience and Director of the Institute of Neurotoxicology. After receiving my baccalureate and doctoral degrees from the University of London, I joined my present institution where, for the past 14 years, I have been a full-time research scientist investigating the actions of chemical substances on the nervous system. I appreciate this opportunity to share with this distinguished body something of what I have learned about neurotoxicology.

May I introduce the subject with two principles, both of which are clearly established and widely accepted:

(1) The nervous system has an enormous biological responsibility in directing and maintaining normal bodily functions and in processing, storing, and releasing information that allows the human being to be unique among mammals. It allows us to think, remember, recall, to have emotion and personality, to act rationally and responsibly, to sleep and to wake, to walk and to run, to see, smell, taste, hear, and to sense touch and pain. All of this --- and much more --- is possible because of the exquisite structural and functional coordination of special cells (neurons) found in the brain, spinal cord and nerves that supply vital organs, skin and muscle.

(2) The nervous system is commonly affected by chemical substances present in the environment. Some of these effects are short-lasting and reversible: the inebriated state that

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follows excessive intake of an alcoholic beverage is familiar to one and all. Other effects of environmental chemicals are long-lasting, permanent and sometimes even progressive. Such changes may occur with single or repeated chemical insult to the nervous system: an example of the latter is the chronic alcoholic who suffers mental deterioration, psychosis and hallucination, tremor and incoordination, limb weakness and abnormal skin sensation. Chronic neurotoxic diseases are almost always associated with structural breakdown of parts of the nervous system, although prolonged imbalance of critical chemical systems used by the brain to transmit information can also precipitate chronic, debilitating neurological dysfunction. The periodic or relentless involuntary movements of the schizophrenic or parkinsonian patient on chronic drug therapy provide graphic examples of the disastrous effects of chronic chemical imbalance in the brain.

It will be apparent from these two principles that we are all are at risk for neurotoxicity, that the effects are often cumulative, and that they may result in devastating neurological or psychiatric disorders that impair the quality of life, cripple, and potentially reduce the highest intellect to a vegetative state. Those at greatest risk include the unborn or newborn child whose brain is inadequately shielded from toxic substances in the blood; the drug abuser who is repeatedly exposed to large concentrations of neurochemically-active substances; the undernourished whose nervous system may already be compromised by nutritional insuffiency; the worker who has a lifetime exposure via skin and lungs to potential neurotoxins; and the aged whose nervous system --- already impaired by the aging process and by a lifetime of polypharmacy and environmental chemical exposure --- is more susceptible to the effects of chemical attack.

I would like to offer some recent examples of chemicals with chronic neurotoxic potential. They include substances in the workplace, in the home, in the general environment, in food, cosmetics and in self-prescribed medicines.

My first example may be surprising: a required vitamin. Vitamin B_6 is freely available in health-food stores in tablets as large as one gram. Repeated use of one-quarter of that dose to ameliorate the premenstrual syndrome has caused walking defects in young women mistakenly diagnosed as having multiple sclerosis. Similar problems have occurred among weight lifters and those persuaded of the "merits" of megavitamin therapy. We learn from

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this experience that the nervous system cannot tolerate repeated exposure to abnormal levels of certain chemical substances, even if they are natural materials and actually required (in doses of 2-3 mg/day) for normal neurological and body function. B_6 megavitamin neurotoxicity could have been avoided, however, if we had heeded the toxicology literature where this phenomenon was clearly demonstrated in experimental rodent studies.

The second example concerns two synthetic chemicals that were generally regarded as safe as artificial flavoring additives and widely employed as synthetic musks in soaps, creams, perfumes, after-shave lotions and detergents. In 1955, AETT (Musk Tetralin) was introduced into fragrance preparations without testing for chronic toxicity and, in 1977, voluntarily withdrawn by the fragrance industry after repeated exposure to the unbroken skin of rats had demonstrated degeneration of brain neurons and structural changes in spinal cord and in nerves supplying the limbs. An unusual early sign was increased irritability, a behavioral change I remember well because the rats had a tendency to bite! We may never know whether humans reacted similarly to Musk Tetralin, although the prospect of a widely used fragrance chemical that penetrates human skin and induces aggressive tendencies by damaging the brain leaves much to the imagination. The second neurotoxic fragrance compound, Musk Ambrette, was introduced in the 1920s, used in quantities exceeding 100,000 lb/year for over 50 years, and has yet to be removed from the market place. Hundreds of other compounds used in fragrance formulations remain to be tested for chronic neurobehavioral toxicity.

There are numerous examples of environmental pollutants that have caused epidemics of neurotoxicity: witness the 20,000 paralyzed by cresyl phosphates during Prohibition, the similar number affected a few years ago by the Spanish Toxic Oil Syndrome; the thousands of adults and children in Japan and elsewhere crippled and/or mentally retarded by methylmercury in food and water; the untold number of inner-city children with brain development threatened by exposure to lead-based paints.

Workplace exposure to chemicals is a frequent cause of serious neurotoxic disease: e.g. lost sensation from acrylamide; partial paralysis from n-hexane; tremor and abnormal eye movements from chlordecone (Kepone); inability to urinate from DMAPN and, most recently, the constellation of neurological abnormalities induced by BHMH. This compound was introduced in 1979 as a catalyst in the manufacture of reinforced bathtubs. After only a few

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weeks of use at a plant in Lancaster, Texas, several exposed workers experienced dizziness, pins-and-needles, muscle weakness, incontinence, memory loss, and disturbed vision. Some of those affected still displayed weakness and sensory loss two years later. The epidemic could have been prevented by adequate premarket evaluation of BHMH because appropriate animal studies conducted after the epidemic demonstrated a comparable disease in rats repeatedly exposed to the compound via their skin. No such testing was required or performed.

In summary, chemical substances with neurotoxic potential are legion. The majority of neurotoxic disease probably results from the side effects of therapeutic and abused drugs, including alcohol, although numerous examples of environmental epidemics, industrial accidents, and ill-advised consumption of purified chemicals, have caused large numbers of individuals to develop overt neurological deficits. These probably represent the tip of the iceberg since more subtle neurotoxic changes go unrecognized. We are ignorant of the long-term effects of substances with neurotoxic potential added to food (e.g. monosodium glutamate, aspartame), present in "skin-care" products (e.g. Musk Ambrette, zinc pyridinethione), or used in the workplace (e.g. methylene chloride). Of the 588 chemicals for which occupational standards are set by the American Conference of Governmental Industrial Hygienists, 167 have direct nervous-system effects as a basis of their regulation (1). Many more will be discovered if we subject the inventory of chemical substances to experimental testing for neurotoxicity.

Reference

1. Anger, W.K. (1984) Neurobehavioral testing of chemicals: Impact on recommended standards. Neurobeh. Toxicol. Teratol. 6: 147-153.

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Mr. VOLKMER. Thank you very much.
Mr. Carsner.

STATEMENT OF FRANK CARSNER, DISABLED WORKER, PORTLAND, OR

Mr. CARSNER. My name is Frank Carsner. I am here as a representative of the Toxic Victims Association, a 1-year-old organization, providing support for people suffering toxic poisoning. I'm also an ex-painter, disabled because of solvent and isocyanate exposures.

I was employed by a large truck manufacturing plant, and in 1981 I made $24,000 a year. My income is now nothing. I was a master painter for 8 years, spray painting large amounts of paint, both isocyanate-based and non-isocyanate-based, and using large amounts of solvents in this process.

I was never ill, except for tonsil removal and surgery on my right knee, until becoming a painter. I was into weight lifting, football, basketball, swimming, and hiking. Now I can do none of these.

Before painting, my level of intelligence, according to my naval records, was above average; now, according to occupational health specialists, it is low average.

Since my exposure, I have been under the care of five doctors: Dr. Rosencrantz, urologist; Dr. Keppel, occupational respiratory specialist; Dr. Linz and Dr. Morton, occupational health specialists; Trostel, osteopath; and Jhaveri, urologist.

Let me stress that before these exposures I had no need for doctors. Now these doctors tell me that my nervous system has been heavily damaged, my brain has been damaged, and I suffer chemically-induced asthma. I also have kidney, liver, and vision difficulties. I had a tumor removed from my eye less than 1 year ago, and have been told that I have more, not to mention the chronic muscle pains throughout my body.

All of the paints and solvents I worked with—all the paints and solvents I worked with induced these problems and have created financial and health burdens for me and my family that, at the age of 39, are almost more than I can bear.

I am currently taking the prescribed medication—I take Asyloprim for my kidneys, Somus for my muscle pains, Medrol, a steroid, and Alupent spray for my respiration. I take Theo 24's for my bronchial dilation.

And what makes me even more ill is that throughout all these years I worked as a spray painter the only notifications I received from my employer concerning the products I worked with were discipline letters for not putting paint numbers on the correct lines on my production reports and for missing work when I went to doctors trying to find out what was making me so sick.

Throughout my entire 8 years at this truck manufacturing company, I was never informed of the hazards of the solvents I used. None of these products were adequately, clearly, or, should I say, truthfully labeled. Yet the hazards for most of the products had been known for years by the chemical manufacturers and other people.

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Now this is not just a problem that only I experienced. My co-workers experienced this, too.

All the painters I know of who have been tested by expert qualified doctors have had neurological damage, central nervous system brain damage. Most, but not all, have had chemical-induced asthma and skin problems, and may I say many more different kinds of problems, too.

Three or four of my fellow workers have died of suspected chemical exposure problems: Dale Hobbs, liver and kidney failure, cancer; Bill Thorpe, respiratory arrest, because he ran out of his medicine. He had chemically-induced asthma, too. Vern Estes—who I found out his name now—Vern Estes, who had cancer of the brain and a cancer in his lungs.

People should be informed on these labels and throughout the training of the real problems that can and do happen when exposed to these chemicals. Currently, product labels may talk about symptoms that you will experience, but they don't tell you that these symptoms are signs of overexposure and that you are at risk to your central nervous system, chemically-induced asthma, cancer, et cetera. They tell you not to drink them. What kind of warning is that: don't drink the chemicals, the paint?

These labels should be designed to protect from the most extreme exposures likely to be experienced by the user. No one knows what adequate ventilation is until it is too late. When we asked the company, they said it was all right, when in fact it wasn't.

Workers are not dumb; they can read, they can write, and follow instructions, if the labels are written out clearly and define clearly the true and existing hazards.

In Scandinavian countries they teach occupational health in their high schools, then continue to teach it in the workplace. Here they don't even teach it in the workplace.

Chemical companies make new and better paints and solvent products each year, but, sadly, they are usually more and more dangerous. And there are many different jobs that use these solvents and isocyanates, such as printers, mechanics, carpenters, and plumbers, even people at home.

The chemicals I used are used throughout the country—hundreds, thousands, or millions of gallons a year. Who knows for sure, but we know it is a very, very big problem.

It is not only a worker's problem, because these labels state nothing of the fact that you can carry the solvents home to your family via your clothing, which leads to toxic exposure and, therefore, related toxic problems to innocent children and your spouse.

And, remember, these solvents are found everywhere—when you strip furniture, polish a floor, or clean your oven. For you, these may or may not cause dangerous exposures, but for me now I can't even be near these products without fear of getting sick. You can't know what it's like, but you can help prevent others from experiencing what I've been through if you require better, more clear labels and instructions and training for the products professional painters and other workers must use. This is a responsibility shared by employers and manufacturers which has for too long been ignored, but I'm glad that you have taken the time to listen to me today.

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Thank you.
[The prepared statement of Mr. Carsner follows:]

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The chemicals I used are used throughout the country, hundreds, thousands or millions of gallons a year. Who knows for sure, but we know it is a very, very big problem.

It is not only a worker's problem, because these labels state nothing of the fact that you can carry the solvents home to your family via your clothing, which leads to toxic exposure and therefore related toxic problems to innocent children and your spouse.

And remember, these solvents are found everywhere. When you strip furniture, polish a floor or clean your oven. For you, these may or may not cause dangerous exposures. But for me, now I can't even be near these products without fear of getting sick. You can't know what it's like, but you can help prevent others from experiencing what I've been through if you require better, more clear labels and instructions and training for the products professional painters and other workers must use. This is a responsibility shared by employers and manufacturers which has for too long been ignored. But I'm glad you have taken the time to listen to me today.

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DUPONT

IMRON

POLYURETHANE ENAMEL

ACTIVATOR

WARNING – FLAMMABLE – VAPOR HARMFUL. MAY CAUSE SKIN IRRITATION. Keep away from heat, sparks and open flame. Avoid prolonged contact with skin and breathing of vapor or spray mist. Wash thoroughly after handling and before eating or smoking. Close container after each use. Use only with adequate ventilation.

192S VAPOR HARMFUL. Mixture contains isocyanates having air contaminant properties equivalent to toluene 2, 4 diisocyanate. A cartridge type respirator, used in accordance with the manufacturer's directions, is recommended when engineering and administrative controls of air contaminants are not possible.

DIRECTIONS FOR USE

To be used only with DuPont IMRON Enamel. Activator volume 192S is available in three volumes each (1 qt., 1 gal. and 5 gal.). To make 1 gallon ready to use material, blend 1 quart of 192S with 3 quarts of color. Keep container closed tightly, since repeated exposure to moisture will cause gelation.

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DUPONT

IMRON

POLYURETHANE ENAMEL

192S ACTIVATOR

FOR USE IN SPRAY PAINTING BOOTHS

DUPONT IMRON IS A REGISTERED TRADEMARK

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Mr. VOLKMER. Thank you very much.

Mr. CARSNER. I'd like to ask one more thing.

Mr. VOLKMER. Yes, Mr. Carsner.

Mr. CARSNER. This workmen's compensation paper here, I'd like to have it—make sure that it's entered into the record. Is that the proper—it's on dangerously defective labeling.

Mr. VOLKMER. That is the material that was submitted with your statement——

Mr. CARSNER. Yes.

Mr. VOLKMER. Yes, that will be made a part of the record.

[Material follows:]

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WCM

WORKERS' COMPENSATION MONTHLY

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Painters: Chemically Induced Asthma

by Douglas A. Swanson, Esq.

New evidence has established that there is yet another risk to those workers who paint. It is the risk of contracting chemically induced asthma. The asthma is caused by exposure to isocyanates, a component of polyurethane, a 2-component paint.

E.I. du Pont de Nemours and Company and Mobay Chemical Corporation manufacture one of these paint systems. Du Pont manufactures Imron 192-S Activator while Mobay manufactures the active ingredient in the 192-S Activator—Desmodur N-75. Imron has gained popularity because it provides a superior wear and appearance under harsh conditions. The component primarily responsible for the paint's extended wear is a compound called hexamethylene diisocyanate which is manufactured by Mobay under the trade name Desmodur N-75.

The medical evidence is now quite clear that exposures to sufficient levels of isocyanates will cause some people (generally 5 to 20 percent of an exposed population) to develop various acute reactions, including shortness of breath, nausea, vomiting and abdominal pain. Exposure can also lead to sensitization so that subsequent exposures result in severe reactions and to a chronic and permanent asthma condition. There is also evidence to show that neurological problems may develop.

Two cases in Oregon are believed to be among the first court trials to have findings issued which detail the dangers of this product. (*Owen P. Kelly v. E.I. du Pont de Nemours & Co., and Mobay Chemical Corporation*, Civil No. 81-166-RE and *Dennis V. Schmitt v. E.I. du Pont de Nemours & Co.*, Civil No. 80-1182-RE).

The cases were tried jointly before the Honorable James Redden of the United States District Court for the District of Oregon. The Judge's Findings of Fact are a harsh indictment of the dangerous substance. The following findings are from both cases:

6. Exposure to sufficient levels of isocyanates will cause some people to develop reactions, which may include shortness of breath, tightness of chest, nausea, eye and skin irritation, vomiting, dizziness and abdominal pain.

7. Approximately 5 percent of the population, when exposed to isocyanates, will become sensitized to isocyanates so that subsequent isocyanate exposures even at extremely low levels, will result in a severe and sometimes fatal reaction to it.

8. Sensitization results in asthma like conditions (e.g. shortness of breath, wheezing).

9. Sensitization is a permanent condition. Once a worker is sensitized he or she must avoid any further exposure to isocyanates at any level.

10. While the asthma symptoms that first indicate that a worker has been sensitized will generally subside after the worker is removed from the isocyanate environment. Sensitization can lead to a persistent, permanent asthma-like state.

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33. Du Pont's label and warnings on the 192-S activator were dangerously defective in the following ways:

a. Du Pont only warned of allergic respiratory reaction when it knew that the 192-S activator could result not only in an asthma-like condition reversible after several hours or days, but a persistent, chronic asthma condition that in some cases would be permanent.

b. Du Pont's warnings did not warn that exposed workers could develop a permanent disease.

c. Du Pont's warnings did not warn of the sensitization phenomenon which would render a sensitized worker hyperreactive to even a very low exposure. The label did not clearly explain that once a worker is sensitized, the sensitization is permanent.

d. Du Pont's warnings failed to identify adequately the hazardous chemical component in its product by indicating that it contained "aliphatic polyisocyanates" without specifying what isocyanate derivative was involved.

e. Du Pont's warnings in regard to the need for respirators are ambiguous and did not clearly indicate that any respiratory protection was required.

f. Du Pont's warnings in regard to respirators were written in such stilted and technical language as to be incomprehensible to the average employer or painter.

g. Du Pont's warnings failed to require absolute isolation of the spray painting environment.

h. Du Pont's warnings recommended a vapor particulate mask respirator when it knew that the manufacturers of such masks had withdrawn their recommendation for use with isocyanates.

i. Du Pont warned only of the danger of monomeric isocyanate in their product when the polymeric isocyanate also constitutes a health hazard.

j. Du Pont failed to provide warnings to use protective measures other than respiratory devices, such as goggles, facial protection, and special protective clothing.

k. Du Pont's warnings failed to contain any advice in regard to pre-employment screening of workers who would come into contact with isocyanates.

l. du Pont's warnings failed to warn workers who would be exposed to their products or such workers' employers of the full nature of the health hazards posed by exposure to their products.

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m. Du Pont's warnings failed to warn employees who might be exposed to its products and their employers of the appropriate safety precautions to be used in spray painting operations of its products.

Defendant du Pont was negligent in the manufacturing and Marketing the 192S Activator when it knew or should have known that it was a health hazard to workers, including plaintiff, who would be exposed to such product.

35. Defendant du Pont was negligent in failing to warn workers who would be exposed to the 192S Activator of the full nature and extent of the health hazards posed by exposure to it.

36. Defendant du Pont was negligent in failing to adequately advise Freightliner (plaintiff's employer) and plaintiff of the appropriate safety precautions to be employed while using the 192S Activator.

38. Defendant du Pont was negligent in failing to warn Freightliner and Freightliner employees that it was not safe to spray paint products including the 192S Activator except in totally isolated spray painting operations.

These findings are significant in light of the multiple defenses raised. The defendants took, and continue to take a very hard line that the product only poses a temporary and short-lived health hazard. The defendants also took the position that even if hazardous, they had provided sufficient warnings on their label, if the warnings weren't sufficient, the workers should have protected themselves with appropriate masks, and if the workers did wear the masks the asthma was "spontaneous [illegible] onset".

All the hazards of these chemicals have yet to be established. These decisions, however, represent an important forward step.

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Mr. VOLKMER. Mr. Packard, do you have any questions?

Mr. PACKARD. Thank you, Mr. Chairman.

Dr. Weiss, in trying to determine causations of certain symptoms or diseases or illnesses, how do you—how can you determine whether they're caused from chemicals they're exposed to or from any other of the multitude of reasons? How can you determine which chemicals and which products ought to be tested before marketed and which ones need not be tested, and who makes those decisions?

Dr. WEISS. You've asked the key question. For an individual case, of course, it's often impossible to determine the source, say, of a neurological abnormality or a behavioral complaint. That's the reason that many of us have called for premarket testing of new chemicals.

The Toxic Substances Control Act, in fact, mandates premarket evaluation of all new chemicals introduced into commerce as well as testing of older chemicals. If we had some notion of the neurotoxic potential of newly-marketed chemicals, then we could more firmly establish a connection between the deficits displayed by an exposed individual and the exposure. In the absence of such information, our ability to make such a connection suffers.

The second way of establishing such connections is to conduct epidemiological studies; that is, to examine through a battery of tests the performance of an exposed population, comparing that performance with that of an unexposed population. This really is the way in which the organic solvent syndrome in Scandanavia has been established.

Scientifically valid studies conducted on both human populations and in the laboratory are the answer to your question. We can't go skipping around from one person to another, because each person has a different constitution and a different history, in order to establish whether a substance is toxic or to establish whether these unique complaints and clinical problems arise from the individual's history and from unique experiences or from exposure to one or a set of chemicals.

Mr. PACKARD. Mr. Carsner, most workers, even when they read warning labels and the fine print on the side effects of some of the things they use—is it true in your judgment that most workers tend to perhaps not ignore them, but not take them seriously?

I was a painter myself, and also—while I was working my way through dental school. And in my dental work I know that, particularly as a dental—in dental lab work you work with a lot of chemicals that I think are almost obviously—have harmful effects if exposure is in the wrong way or over a longer period of time. And even dental lab technicians, painters, and others will read the labels, but they get still caught up in their work and often ignore it or do not personalize it, and do you think that that's common among most workers?

Mr. CARSNER. Well, I think the problem lays in the fact that it's not—the label is not—it's stilted to make the product seem more—or less harmless—less harmful—than what it is. It is obvious that the labels that I showed you there, they aren't even recommending respirators. They're telling people that haven't even heard of isocyanates before Bhopal, India, you know, you've got isocyanates in

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this product. Well, now, what's isocyanates? You have to understand what it can do. It doesn't say that it can destroy your central nervous system; that it can cause skin cancers, and et cetera. If that were on the label, you can bet your bottom dollar that dental technician is not going to just set it to the side, the regulations, or what to use. If you don't understand what adequate ventilation is, how are you going to worry about whether it's adequate or not? If you have no understanding of what engineering is—it's not very clear on the label at all, except for the fact that it's harmful if swallowed, and anybody can figure that out.

Mr. PACKARD. You stated in your testimony that your employers reprimanded you for going to physicians for—simply to find out what the problems were. Does—do you think that that's a common situation, where employers are reluctant to even have employees find out what causes some of their problems or is that simply a unique situation in your case?

Mr. CARSNER. I don't believe it's a unique situation, unique in the sense that I'm not the only person in the United States that has been reprimanded and discharged for my concerns on safety and my health.

Mr. PACKARD. What was your employer's reaction when they found out that you had serious problems that could be related to their—to your employment?

Mr. CARSNER. Well, again, this is in my opinion. I believe the employers at least had a reasonable knowledge that I was being, as I say, chemical ties to the—toxified to the chemicals while I was still working there and going to the doctor. That's my opinion. They have industrial hygienists there. They have to have some understanding of at least the basic problems involved with solvents, which we did not. So I believe they knew the problems that they had, and for monetary reasons didn't want to deal with it.

Mr. PACKARD. Were they checked and reviewed by governmental agencies that are in charge or responsible for health safety, OSHA or other agencies?

Mr. CARSNER. APD went through. APD didn't have—I've talked to ex-APD investigators, and they didn't have working knowledge—this is a common thing. They went through the plant, the company comes through—it's probably typical everywhere—the company comes through a couple of days ahead of time and tells you—or the day before, and I've had the morning of an inspection, and say, "Make sure all this is covered and this here. Take the time to put it on there." And then when they walk through, they walk through with the APD man and they can walk by faucets with thinners leaking out of it and not recognize this. So I don't believe that most of the agencies are prepared, trained, or have the concern to.

Mr. PACKARD. In your testimony you mentioned that the products were not labeled properly or, as you put it, truthfully. Did you—are you aware of any circumstances where labels were altered by your employer or where they did not reflect standard requirements and followed regulation? What was on the labels or do you recall if anything was on the labels?

Mr. CARSNER. Well, the problem with—I recall now. Of course, I've been involved with this for quite a bit. The problem with the labels is—and this is close to my heart because, you know, all they

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would have had to have done for a few dollars, I could have had—and I don't mean this as a sympathy thing, but I could have had my health.

Now the labels recommend a respirator of this type here [indicating picture]. I'd like to pass it up here. And this is untrue. The respirator manufacturers have never at any time—and this is at our truck manufacturing plant there in Portland, OR, and that's a person I painted with. That's the exact uniform that we had to paint with.

[Pictures follow:]

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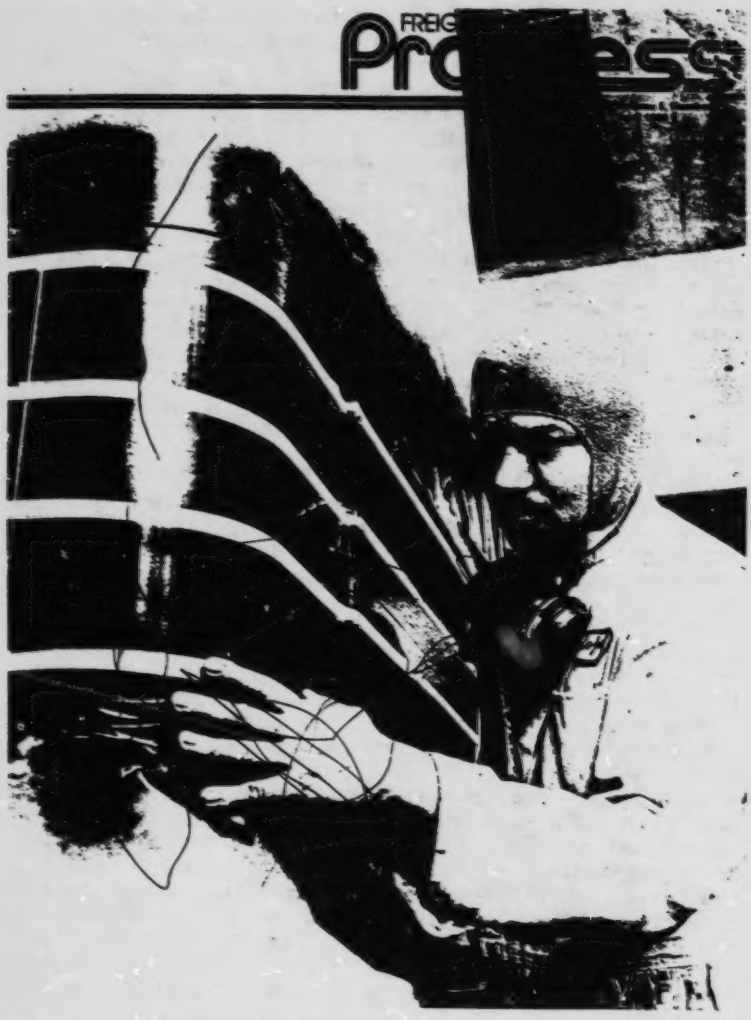

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This is what the particular company—product that we were using recommends now to nobody but people that can get to the paint suppliers. All right? The painters themselves have never seen, never heard of these suits.

Now the labels have been—first, they started out—can you see that clearly? That's an air line respirator. That's a chemical-proof suit, and it doesn't show it, but 10 to 1 he has chemical-proof boot covers. He's got a full face shield covering his eyes to keep from any paint going in, from going in through the eyes, and none can get to his skin. Special chemical-proof gloves that will stop the absorption of the solvents. The man looks pretty safe to me.

And then you look at the one I sent up there and you've got cloth everywhere, which, you know, does not stop chemicals or fumes, or et cetera.

On the labeling here, the labels first started out with—and 1970 is the earliest one I have here for you—and there is no reference to a respirator, period, vapor particulate or in-line air respirator.

It goes on for a couple of years like that, still no respirator recommended. A 192–S activator, a product that's isocyanate-based catalyst.

And then we had in 1972—it still doesn't say to wear a respirator. In 1973, it says you don't need to wear a respirator unless there is bad ventilation, then to wear the vapor particulate respirator, which is not recommended—I'd like to emphasize is not recommended by any respirator manufacturer, the vapor particulate respirator.

Now they're saying if it's real bad and you're in a room like we were, we shot inside of a cab truck right at each other, two painters, and you couldn't see. You shot by sight. Well, if it gets that bad, I guess you're supposed to put on a vapor particulate.

Now it goes on that people are having more and more troubles with these paints, physical problems, and some people are catching on.

Then it drops down here to 1976. Now you wear a vapor particulate respirator if the administrative controls are not feasible—just what I just said. I'm sorry, I didn't mean to be redundant, but it was another label.

Then later in 1976 they come up with that—wear the vapor particulate respirator if everything is OK, and how you're supposed to tell, I don't know, and to wear an in-line respirator if it's bad air, bad ventilation. Finally, they're getting to the in-line respirator, and I believe that they've known this here for many, many, many, many years.

The problems with the isocyanates, et cetera, got to this chemical company in, I believe, 1957. There was a German study done on it and the information was available to them. That's my—thank you very much. Have I answered the question?

Mr. PACKARD. Fine. Thank you.

Dr. Spencer, I think Mr. Carsner brought up in his projecting the transition that has taken place over the last several years the fact that public awareness of these kinds of health safety things has been gradual evolvement rather than a scientific and study-oriented process. I think there is a much higher public awareness now of

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problems and measures that can be taken to prevent health—long-term health effects.

What, in your judgment, is being done now to address these concerns compared to what it was a few years ago? We had the same problem with black lung, with asbestosis. There was little attention given to those causative programs until I think public awareness was raised. In this case it's very likely that in many of these neurological toxic problems public awareness is now much greater than it was, and, therefore, perhaps maybe more Government agency action or other private sector action is being taken.

Are there something that we're not doing as well now as we could or should be doing with what level of information and interest we have?

Dr. SPENCER. Mr. Packard, of course, you're absolutely right that as society as become more sophisticated we have learned that long-term, low-level exposure to chemical agents can, indeed, induce, as we refer, target organ damage, including brain damage.

As we become more sophisticated, we can begin to look for cause-effect relationships between occupational exposure for x years to a particular agent and then some many, many years later the development of some brain disorder, but the level of sophistication has to grow a lot more before we can pinpoint that with any degree of efficiency.

We know, for example, as a result of a recent outbreak of Parkinsonism among Californian drug addicts that chemical exposure can induce this type of major neurodegenerative disease. In fact, if those same people had been exposed to very much lower levels over a period of 10 years, it's very doubtful if the same cause-effect relationship would have been made.

And so we have to begin to look much more carefully for possible cause-effect relationships. This is done at various levels which I'll try and address this afternoon. Rather than go over the same materials, I'll present it at that time.

To answer the second part of Mr. Packard's question, I think certain agencies such as the National Institute of Occupational Safety and Health have, in fact, taken the lead in the area of behavioral and neurotoxicity and have, through various methods, increased public awareness of this potential problem, both through publications from intramural personnel available in the scientific literature, one of which I have here, or through the placement of grants for research on the extramural program.

The National Institute of Neurological Communicative Disorders and Stroke, through their extramural program, is also aware of the link between chemical exposure and neurological disease.

The National Institute of Aging has recently got into the act and held a conference commissioned by Congress just last week to address the concern, No. 1, that a lifetime of chemical exposure may advance or speed the aging process and, second, that the aged individual may be more susceptible to chemical substances.

On the other side of the coin, there are other agencies who seem to have been reluctant to take this subject as seriously as it might be taken. I gave an example of AETT, a fragrance compound which was widely used for many years, but it fell to industry, in fact, to initially make the link between chronic exposure of animals and

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neurotoxicity, and I was privileged to get in on the act later on and demonstrate that, in fact, it was a neurotoxic component and, with that evidence, industries took the information to FDA and voluntarily withdrew the material from further use.

Now it's significant, I think, that FDA, as far as I'm aware, chose not to regulate on that particular compound, so it can be introduced at any future time.

The second example I gave was musk ambrette. Now, in fact, the FDA had stumbled across this compound and placed an abstract in the toxicology literature indicating that this produced some strange walking difficulties in rats exposed to the material, but it failed to follow it up and it fell to industry again actually, a different branch of industry, to proceed with studies in this area and to demonstrate that it was a neurotoxin, and this information was taken to the FDA.

Mr. PACKARD. Let me interrupt you just for a moment and ask you, is it common or under what conditions is it possible for a product to be marketed without going through a certain—in your testimony you indicated that some have been put on the market without testing, and obviously others are required to have testing. What determines whether a product should be tested and whether it can be marketed without testing?

Dr. SPENCER. A good guess determines.

Mr. PACKARD. There are no regulations that would apply to any chemical substance that's put on the market, whether it be a fragrant product or whether it be an industrial product?

Dr. SPENCER. I should preface my remarks by saying that I'm not an expert in this area. I can tell you that pesticides are tested regularly by EPA and food additives are subjected to rigorous tests, as far as I'm aware. I stand to be corrected on that if I'm wrong.

However, I would point out that—I will point out that many of the tests which are utilized employ short-term acute toxicity studies: How much of this compound can we—is required to kill the animal or half the population of animals?

We have failed to realize in a way that we must realize the association between much lower levels of exposure, chronic exposure, over a lifetime and the possible effects resulting therefrom. This level of sophistication is growing, but we are not yet there.

Mr. PACKARD. Let me include Dr. Weiss in this question, both, and Dr. Spencer. Do you think our problem is greater in home products, home use, or in the industrial area? Dr. Weiss?

Dr. WEISS. I think it partly depends on which kind of industry you're designating. The Kodaks and the Dows maintain huge toxicology staffs and monitor very carefully. A lot of the exposures, as you just found out, in industry that present potential problems occur in small companies without either the resources or really the consciousness to conduct monitoring, both in the workplace for exposure levels, and monitoring of the health of the workers.

For substances of the kind that Dr. Spencer described, it's essential, except for catastrophic exposures that produce anesthesia, to monitor workers over a period of employment lasting several years to determine whether or not progressive changes are occurring.

As you might imagine, monitoring in the home environment, of course, takes place not at all and without any controls. People who

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strip furniture, for example, with potent solvents may be affected. If they do it consistently, they're essentially exposed chronically to very powerful chemicals.

The Environmental Protection Agency, as you probably also know, is concerned with indoor air pollutants, which seem to be a bigger threat in some cases than outdoor air pollutants.

Mr. PACKARD. I think it gets back a little bit, also, to what I was asking Mr. Carsner, and that is, do people read the warning labels? Now most products are not going to have crossbones on them with warning labels saying you can die from this substance. They just won't go on the market that way.

Dr. WEISS. Yes, but it depends on the degree of public awareness. For example——

Mr. PACKARD. It's small print. Many of us read instructions, but we don't read the precautionary print.

Dr. WEISS. Well, even with these—referring to his glasses—I can't read the small print anymore. [Laughter.]

Mr. PACKARD. My wife certainly would not normally read the precautionary areas on an oven cleaner, for example, or some spray that she would put on a pan.

Dr. WEISS. It depends on the level of public awareness. Let me return to the area of food additives. In food additives, testing is conducted mainly from the standpoint of what I told Mr. Simon—it's carcinophobia. Now the levels, say, for a 2-year feeding study in rats or mice for a food additive are hundreds of times, sometimes thousands of times, higher than the levels to which a human would be exposed. That's partly because of the Delaney amendment and the 1958 requirements of premarket testing.

But now we have evidence that adverse behavioral responses to food colors can be produced in animals at levels prevailing in the diet, and of course we have the most important evidence of all, responses in humans. And, yet, the FDA has not acted.

In part, I think, that lack of action is a lack of seriousness about neurotoxic and behaviorally toxic responses; in part, also, I think it's due to the fact that at those dose levels only a fraction of the population responds, say, 5 percent or 10 percent of children. That does not trigger the same concern, partly because of the way the FDA and other scientists approach the evaluation of data. They just don't seem to respond in the same way to an exposure that produces responses in only a small fraction of the population, partly because the experimental designs and statistical techniques on which they rely are not sensitive enough to detect responses only in a small proportion of sensitive people.

Mr. PACKARD. Mr. Chairman, I've taken more than my time. I appreciate it.

Mr. VOLKMER. Yes, I have several questions. I think I know the answer to the first one from the answer of Dr. Spencer to one of Mr. Packard's questions, but many health effects that are linked to chemicals, and especially exposures in the workplace, these risks must be regulated by the Occupational Safety and Health Administration. However, OSHA can only issue a new standard for a substance if the substance presents significant risk to health. If a worker doesn't receive a large dose of a dangerous chemical but instead a small exposure on a daily basis over a long period of time,

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how does that pose a significant risk to health that can be regulated by OSHA? Dr. Spencer or Dr. Weiss?

Dr. WEISS. A significant risk to health is found in one of two ways: either by observations on workers themselves or by laboratory studies. It's only recently that laboratory studies have begun to play a major role in the determination of hazard, but, even then, as my colleague pointed out, the emphasis has been on short-term testing, not on long-term testing.

There are two reasons for the lack of long-term testing: a reluctance on the part of investigators and a reluctance on the part of funding agencies. You don't build a career, as you might imagine, publishing a paper on long-term tests in rats. That takes about 3 years to conduct. Funding agencies are reluctant to support long-term testing which even in small groups of animals over a period of 2 or 3 years, could require half a million dollars. So you have joint neglect based both on the investigators and the funding agencies.

I think probably the way to handle that problem is to try to incorporate neurotoxicity testing into the usual cancer regimen with, say, a 2-year exposure study, and also to probe further into mechanisms which eventually will give us answers that we can generalize to many other substances or classes of substances even.

The workplace problem presents even more difficulties because that means following the history of individual workers over a period, say, of two decades. Almost all of the information we now possess comes from cross-sectional studies. That is, evaluation of workers who we presume in the past have been exposed to various levels of the substance. But, as you are aware, workers are not exposed to single substances in laboratory purity; they're exposed to combinations, another problem with which both the agencies and now the National Academy of Sciences are grappling; that is, the evaluation of complex mixtures.

Obviously, the strategy has to be multifaceted. We have to begin requiring testing of new chemicals and old ones about whose hazards we're suspicious, and also to monitor workers in environments that allow us to define exposure, and, also, to monitor workers with advanced test methods and not simply the relatively gross clinical criteria whose aim is only the detection of frank, adverse, and possibly irreversible effects.

Mr. VOLKMER. Dr. Weiss, would it be possible, then, for EPA or FDA, when conducting tests for carcinogenicity on laboratory animals, to have an investigator simultaneously investigating the effects of those same chemicals at the same time on the toxicity effects on neurological system?

Dr. WEISS. I think it's possible. Some years ago I was a consultant to the National Center for Toxicological Research, and, at that time, when the Neurotoxicology Division was being planned, at the same time we were also considering protocols that would integrate neurotoxicity testing with carcinogenicity evaluation at a much lower cost than performing the same investigations independently.

Mr. VOLKMER. Dr. Spencer, do you have any——

Dr. SPENCER. I think it would make eminent sense to have access to those extraordinarily valuable animals that have been subjected to the 2-year exposure to agents being tested for carcinogenicity

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and access to those to determine possible adverse effects on the nervous system and, indeed, on other organs. For some reason, there has been a great reluctance to make those animals available.

Mr. VOLKMER. OK, Dr. Weiss, my staff informs me you once gave an address which you entitled, "Help Wanted: 25,000 Behavioral Toxicologists." Is that correct?

Dr. WEISS. That's correct.

Mr. VOLKMER. What did you mean by that?

Dr. WEISS. That was an address I delivered to a regional meeting of psychologists. The purpose of that statement was to point out the enormous galaxy of problems that were susceptible to investigation by a science that had developed over the past 100 years. The questions keep bubbling up almost volcanically as we investigate more and more substances with more and more techniques.

To investigate even a slight number of questions aroused by almost any single agent requires a strategy built on many different kinds of tests, many advanced tests, many complicated questions, many new techniques, and many different specialties. And, if you start adding up all of the different questions, you find that you need many different specialties, many different techniques, and pretty soon you've reached 25,000.

It was meant as a joke, but I find myself not really joking about it anymore.

Mr. VOLKMER. Is the Government—and by that meaning the various agencies involved with research or with the problem of neurotoxicity—helping in research on your toxicity?

Dr. WEISS. Most of——

Mr. VOLKMER. Maybe helping, but to what extent also?

Dr. WEISS. There are two kinds of laboratories—or three kinds of laboratories—conducting research: Government laboratories, industrial laboratories, and university laboratories. It seems to me that the most reliable long-term information, that is, the development of a collection of data to which we can turn in future years, comes from the university setting. The university setting is also especially valuable because it's a resource that provides new minds. The university flourishes because it provides new investigators.

In the current attempts to constrain Government spending, I think it's the universities who have suffered the most. And for that reason, despite the eagerness of the funding agencies such as the National Institutes of Health to support work in this area, the restraints on spending have meant a very slow evolution in knowledge and in our ability to conduct even the most important immediate research for the protection of public health.

It's almost as though we have in our population a marvelous vehicle on which we have failed to conduct preventive maintenance.

Mr. VOLKMER. Dr. Spencer, in regard to the case I believe you mentioned in Lancaster, TX, was the risk to the workers there significant or was it quickly and easily detected, and then were the effects reversible?

Dr. SPENCER. The story of this compound is that it was introduced into commerce with only the type of testing that we referred to, these short-term, high-level acute toxicity tests. In fact, those tests revealed a striking neurotoxicity, but it is always very difficult to discriminate between the agonal responses of an animal

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dying acutely from the possible long-term significance for the nervous system.

Anyway, as a result of that experience, the manufacturers and the EPA did not consider this was a potential problem, and it was introduced into the factory, and in fact remarkably quickly, within a period of only a few weeks, it started causing serious problems, first among one operator who was then replaced and then the second operator came up the line. It was almost like a battle line: He or she fell down and the next one came up and held the pipe, and then—and so on and so on. It was a miniepidemic.

The reason it was recognized so rapidly is that it was such an acute and potent neurotoxin. If, by contrast, this agent had been less potent or had been exposed to the workers in smaller quantities, and the effects had occurred over 10 years or 20 years, as we know indeed such—we do, indeed, know that compounds will produce this type of effect over a long period of time. Had it been that way, it undoubtedly would not have been recognized, because after year 3 one worker would have left; after year 5 one worker would have gone to his or her private physician; and then 7 years later another couple would have gone, and it would have never been recognized. And this is probably the story that is occurring time and time again in relationship to many different chemicals in the workplace.

Physicians do not recognize many epidemics because they're not trained to recognize long-term toxic effects. We don't teach them that in medical schools, and because I guess the American worker is able to afford a private physician an individual often goes to different physicians within a community And since they then talk to each other, the epidemic will never be recognized. There are many factors, therefore.

The reason it was recognized in Lancaster, TX, was because the chemical was a very potent one; it caused a uniform effect in several people, and because it had been recently introduced into the plant, it was immediately suspect on epidemiological grounds.

The experimental animal studies that have followed demonstrated, in fact, that an identical pattern of change occurred in the animals' nervous system once the animal had been exposed repeatedly over a period of several weeks. So, in fact, had the compound been tested in the appropriate way prior to marketing, it would have been shown to be a potential problem in the workplace, and the whole disaster would have been prevented.

Mr. VOLKMER. All right, then, it appears from your testimony that most of the physicians that are out there that would normally be treating people who are getting sick and coming in are not really trained to make a determination as to the neurotoxic effects of chemicals or any other compounds; is that correct?

Dr. SPENCER. Probably I would say that's true.

Mr. VOLKMER. There are some, I'm sure.

Dr. SPENCER. There are remarkably few individuals who have toxicology training in medicine and who are sensitized to the possible problem of neurological effects or behavioral effects, psychiatric effects resulting from occupational exposure. They are well aware that this can occur as the side effects of drugs, but they, for some reason, don't put two and two together; nor do they ask searching

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questions about exposure history, chemical exposure history, when a patient turns up in their office.

The astute physician may, indeed, ask what the occupation is and the more astute physician will go in perhaps and find out exactly what the individual was exposed to, but, by and large, physicians are not trained to search the history in the way that they should.

Mr. VOLKMER. Well, who is in a position to detect the early symptoms of neurotoxicity? Dr. Weiss or Dr. Spencer, who can we rely on to do this?

Dr. WEISS. I agree with Dr. Spencer that the degree of training in occupational hygiene among American physicians is abominably low. We have sacrificed the portion of the curriculum that ought to be devoted to environmental and occupational health to other pressing questions.

As some of you may know who had any contact with medical school curriculums, there are pressures and demands from every specialty, and so the curriculum committees give in to whoever exerts the most pressure and who makes the best case.

In contrast to European medical education, I think American medical education has a great distance to travel to make physicians aware of the most important elements of health in the community.

I referred before to the woman who was suffering from mercury poisoning. Well, she went from physician to physician in her own community asking for help. Well, a busy physician seeing a 50-year-old woman complaining that she's not herself has the first instinct to prescribe a tranquilizer, and we've seen that over and over again.

Now, medical directors of large companies, as one of the people here attending the hearing can testify, are becoming more and more aware of the problems of behavioral and neurotoxicity. And I think it may only be a few years before some companies adopt strategies, adopt programs, for trying to intervene at the early stages by adopting certain new kinds of assessment methods. But it's going to be a long time before it penetrates to the community physician.

I think one of the most important recommendations your committee could make is to elevate the level of training in occupational medicine in our medical schools.

Mr. VOLKMER. Thank you.

In regard to some of these neurological effects that you've talked about, the use of chemicals, et cetera—and Mr. Carsner, undoubtedly, has experienced it himself—what about the irreversibility of these effects? I'd like to have some testimony on that.

Dr. SPENCER. It's important, I think, to realize that the nervous system is such a complex organization that it has a multitude of possible targets of chemical substances. As I said in my testimony, some may produce rather rapidly reversible effects once the material is withdrawn. Those agents which cause structural changes in the nervous system may also be partly reversible or irreversible. It depends which part of the nervous system you hit.

If one causes a little bit of degeneration of a nerve in the leg, the peripheral nerve has the capacity to regenerate and to restore

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functional connection. However, that nerve may be subject to or more susceptible to repeated attack. We don't know the answer to that question.

By contrast, if we knock out, as this particular fragrance raw material did, AETT, if we knock out a part of the brain in the motor cortex, for example, one may not recover from that because there is something very special about the nerve cell, and that is it is unable to divide like a liver cell or a blood cell, an incompletely-formed blood cell, I should say. And if one loses a nerve cell, that's it; one cannot replace that number. As one depletes these nerve cells, it is suspected throughout a lifetime of chemical exposure eventually the result of this is expressed either by subtle behavioral changes that Dr. Weiss has alluded to or more frank neurological deficits.

Very few compounds, in fact, may have progressive effects, even leading to terminal illness. The best one recognized here is carbon monoxide, but at extremely high levels, I might say. An individual who wakes up after being exposed to an anesthetic level of carbon—who wakes up from a carbon monoxide poisoning episode may appear to be normal for a couple of weeks and then undergo a progressive decline until he ends up in vegetative state and then dies from some infection.

So there is a whole spectrum of different targets in the nervous system. Unless we actually dig in and look to see what's going on, we won't be able to tell whether it's a potentially reversible effect or an irreversible effect.

Mr. VOLKMER. Dr. Weiss.

Dr. WEISS. I'd like to add a few statements to Dr. Spencer's statement. As he indicated, the nervous system contains a great deal of reserve capacity. We may not even be aware of destruction within the nervous system until we reach the limits of that reserve capacity.

For example, he discussed a chemical called MPTP, which is a contaminant of designer drugs and which many of us think is going to lead in the future to a huge epidemic of Parkinsonism among certain elements of the drug addict population.

In a recent study, published I think in Nature, some of the addicts in California were tested by a noninvasive procedure known as positron emission tomography; that is, a technique that allows one, like a CAT scan, to determine some features of brain structure and chemical fucntion. These addicts who consumed the contaminant show evidence of brain damage, not severe enough, however, to be expressed in overt, clinical disorders.

But we know that as the brain ages, those parts of the nervous system that seem to lose capacity, enough to be expressed as overt Parkinsonism during the later years, are even now suffering from a decline. And the best guess you could make now is that these addicts will suffer Parkinsonism earlier than we generally find Parkinsonism appearing in the population.

A well-known neurologist in Montreal has even speculated that, because of the structural similarity of these contaminants to certain pesticides like paraquat, it's possible that, at least in some individuals, Parkinsonism may be an environmentally provoked disease.

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Dr. SPENCER. May I pick up on that, because it pertains to the previous question?

Perhaps it might not be appreciated by the Congressman that the recognition that a chemical component in street heroin causing Parkinson's disease or Parkinsonian state comes like a lightning bolt to the medical community.

The neurological community, in particular, was incredibly surprised to learn of the possible association between chemical exposure and Parkinsonism, because it was widely hypothesized that this was a viral disease or some other entity precipitating the Parkinsonian state.

What I said about lack of training is pertinent here because, had we had the opportunity to teach the physicians that the worker back in 1910 exposed to carbon disulfide also had predisposition to Parkinson's disease, the physician would have seen very clearly the possible association between chemical exposure and this particular devastating neurodegenerative state.

Now, suddenly, with this new awareness, the neurological community is beginning to ask questions about other disorders such as Lou Gehrig's disease, Alzheimer's disease. Could this possibly be the result of chemical exposure?

Dr. WEISS. Yes; I would like to insert just one more statement. About 13 years ago I wrote a paper on aging and the nervous system, and its possible—and possible contribution to accelerated aging by environmental poisons. I at that time was especially interested in methylmercury.

But with a colleague, we made a calculation that if the loss of neurons, which is natural, over time were accelerated by a rate of one-tenth of 1 percent per year, after a 50-year exposure, say, between 25 and 75, the brain would have aged by, say, 15 additional years, by a process we could never detect.

Mr. VOLKMER. Thank you very much. I appreciate it.

Mr. Carsner, what was your eyesight, if you know, at the time you were in the service before you went to painting?

Mr. CARSNER. My eyesight was—I have amliophia in the right eye, which means I don't use it. The layman's term is lazy eye. My left eye was perfectly well, 20/20.

Mr. VOLKMER. What are—I notice that you had to have assistance in reading your statement. What is your present eyesight in your left eye?

Mr. CARSNER. I might throw in something here about the medical observation that was taken on the painters, just explaining the eyesight. They had me written down as 20/20 in both eyes, which was not true. That's just a type of chemical analysis that was done on us, you know, the doctor's report.

The reason—the problem I have is that I have went and got glasses a few years ago when I was still employed there, but I was having the same problem that I'm having now. It was more distinct then. It is that I can be set for glasses, I can go into the machine and, if he gives me time, I can focus on what it is if he sets it, and then I can turn around and the same thing, in 15 minutes or 20 minutes—you know, it's not a predictable—to me, it doesn't seem a predictable. I can't focus at that same level. So I just gave in and got me one of these [indicating magnifying card], so that I can

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adjust it to wherever I'm seeing, the light condition or whatever. That's the problem I have with the eyes now.

Mr. VOLKMER. As I understand it, you are also sensitized to isocyanates; is that correct?

Mr. CARSNER. Almost any chemical with a strong aroma—the term, I forget—solvents. I react violently to solvents. Nail polishes, acetones, everything but flowers and stuff; they don't bother me. Glues.

Mr. VOLKMER. Before you were a painter or while you were painter, did the word "isocyanate" mean anything to you?

Mr. CARSNER. Absolutely nothing. I knew not what it meant any more than I did engineering, proper engineering.

Mr. VOLKMER. There wasn't anything on the labels pertaining to specific, as I've read those labels you've furnished us, specific areas of risk, health risk; is that correct, except for skin and eyes——

Mr. CARSNER. Irritation.

Mr. VOLKMER [continuing]. And irritation to the skin, and possible eye damage, and that type of thing, and not to inhale it or to drink it or things like that?

Mr. CARSNER. Or osmosis or to ingest it——

Mr. VOLKMER. Right.

Mr. CARSNER. It doesn't warn you that it goes through the skin and into your blood, into your liver and kidneys, and et cetera. It doesn't—it's just very vague, an irritant. Now smoking is an irritant, a possible cancer-causing; right? But smoking won't do you in. If you did as the label recommends, as it's stating in there—if you went in there and pulled a gun with big fans in there and you pulled out that gun and shot it without that respirator, you'd be a dead person. This is adequate engineering? What—something to remove it all from the end of your spray gun, or you're going to get it, a certain amount. Just mixing the paint you are. It says nothing about mixing the paint.

I furnished the labels there.

I don't think even the last one—I'm not sure on that, but I don't think even the last one says to wear that air line respirator while you're mixing it, and that's when it's cooking off. You've poured it in there and it's doing a chemical reaction.

Mr. VOLKMER. All right, Mr. Carsner, as you know, anything that the Government does to protect worker health cost some money for industry and eventually for the consumer. In other words, if it was required at the time that you were painting that you had the in-line type of equipment, as you've shown us here, this is of course more expensive than nothing or this type of equipment; you agree on that?

Mr. CARSNER. Oh, I agree, it's more expensive.

Mr. VOLKMER. And, now, I'm not—I just want to know—the question, then, is: How do you feel we should balance the need to protect workers' health with the need to keep the cost of our precautions within reasonable limits?

Mr. CARSNER. Well, for one thing, I think that what is the interpretation of reasonable limits——

Mr. VOLKMER. I agree on that.

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Mr. CARSNER [continuing]. Genetic mutation of children, you know; coming out with—you know, you've got a lot of things to balance here.

We as a group—and we have people that I have talked to and communicated with—we love to see a million freightliners going down the road: Du Pont with the best, shiniest paints and Sherwin Williams and all of them. Profits make the world go around, but the profit, the amount of profit, the amount of expense that it takes to put in that equipment, the amount of expense it takes for education, I'm sure, can be absorbed into the profit of the manufacture of the chemicals and the manufacture of the products that are using these chemicals without any undue burden on them.

You take the air line respirator; you're looking at a unit for two men—for two men. That's two lives and possibly their families' lives, you know, that you're bringing it home from work.

You're looking at the gear on that picture. It's got to run under a thousand dollars for two men, under a thousand dollars. Now how much is that versus the corporation's profit? Of course, that's not the whole answer. There's adequate booths, you know, that needs to be to education of the worker——

Mr. VOLKMER. How old are you, Mr. Carsner?

Mr. CARSNER. I am right now 44.

Mr. VOLKMER. And you have been unable to work for how long now?

Mr. CARSNER. I've been unable to practice my profession way before I went and left work probably, you know, in a safe manner. I haven't worked for 4 years.

Mr. VOLKMER. Four years. So approximately, if you live a normal life span, there's a good possibility that you will not be productive for a minimum of approximately 30 years?

Mr. CARSNER. Well, I try to be productive.

Mr. VOLKMER. But I mean to that extent—your type of occupation for that company.

Mr. CARSNER. Right.

Mr. VOLKMER. And there's others in a similar situation; is that correct?

Mr. CARSNER. Many others.

Mr. VOLKMER. And that would buy a lot of these in-house air line respirators, wouldn't it?

Mr. CARSNER. Yes, it sure would. That's the point that we would like to make.

We have several examples in Oregon alone that this little toxic victims' association that we put together to try to aid some people in assistance, information assistance, chemical assistance—that isn't available to the average person. We put it together, and they call us.

We have a company that works on vulcanizing. They make these conveyors. I'd like to tell you this, because we're not out for litigation, for all this. We'd just like to have some sense made out of this chemical misuse.

This company, the vulcanizing company—and I was going to try to remember the name; I have the problem, but I could furnish that later—they adopted—the man came to me and he said, "Frank," he says, "That stuff that you worked with, I've seen that

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on the labels of our cans, on the glues, the vulcanizing things," and they were using some solvents. And so we dug up the information on the solvents and the isocyanates and furnished them to him, and he had more guts than most people have. He went to the employer and he told them, "Look, this is the stuff we need. It says right here in black and white." We dug this information up for him, MSDS's, and et cetera, some solvent books.

The company at first they said, "Oh, that's going to cost us a fortune. We can't do that. We've got our profit to look at." So he came back, and we've just all got one oar in the water, as I like to say. So it took time. We dug up the costs on this for him, what it would cost for—it's not adequate for isocyanates but it's good for the solvents; right? The respirators, the proper type, and whatnot, and now they use the respirators; the work areas are cleaned up; they weren't before. No matter where these conveyor belts went, the stuff was left in there and they'd have to dig it out. We got a little occupational hygiene and health entered into this.

This company, whatever jobsite we go to, and they put these conveyors in different gold mines in California and warehouser things, and it's all cleaned up now. And it's not costing the company that much money. In fact, it's saving them because people are going to learn sooner or later here what these chemicals do to you and the different exposures, and somebody's going to be paying for it. And they can either pay for it now and have healthy people, pay a lot less money, or they are going to be paying, as you say, for them to exist in whatever form that——

Mr. VOLKMER. I have—do you have any questions?

Mr. TRAFICANT. Yes, Mr. Chairman.

Mr. VOLKMER. I'll recognize the gentleman from Ohio.

Mr. TRAFICANT. Thank you, Mr. Chairman.

We heard some discussion earlier, at least I did, when we talked about the ingestion of particular chemicals such as tranquilizers after a physician has seen a patient that is exhibiting some sort of dysfunction or ill health, and we talked about the toxicological problems that could ensue from that.

My question is, have there been any studies relative to the ingestion of alcohol and/or other drug substances by people in the workplace abusing these particular drugs that with compounded with and exposed to some of these toxicological effects have a synergistic reaction which makes them more, in fact, prone to serious chemical disorder than would the normal person exposed in the workplace? Have there been any studies at all relative to the synergistic effects and the presence of strong abuse factors in the workplace that exist today? I open it up for both of you.

Dr. WEISS. Well, alcohol and tobacco are both notorious. As you probably know, the risk of lung cancer is elevated in asbestos workers. The risk of lung cancer is elevated in people who smoke. When you combine the two, the elevation is just enormous. So that a person who both smokes and works in an asbestos environment has a risk of lung cancer, say, 100 times that of the nonsmoker and the person who is not exposed to asbestos.

The smoker who also, say, is exposed to arsenic also experiences an elevated incidence of lung cancer. Alcohol is able to multiply the risk of exposure, say, to carbon tetrachloride, a widely used sol-

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vent. Alcohol probably elevates the risk to various neurotoxic substances, although those kinds of studies have not been performed.

Only recently has our consciousness about mixtures been raised because it's dawned on everybody that, unlike the laboratory, the real world exposes us to enormous numbers of substances all at once.

In the sterile limits of the laboratory we expose an animal to one substance at a time, feed it a superb diet, and offer it high quality medical care. That certainly is not the case in the environment.

I first became aware of it in my work on the problem of behavioral effects of food additives where, of course, children don't consume one, they may consume several hundred. They don't consume the NIH 07 diet, which is something that Prevention magazine would laud. They consume potato chips, soft drinks, candy, and, in general, a low-fiber, low-nutrient diet, even in families that are conscious of diet.

So your question is very much to the point because right now a National Academy of Sciences committee is looking into how to deal with chemical mixtures, and it's an enormous problem, because in your drinking water here in Washington you probably have something like 2,000 organics, most of which have not been identified.

Mr. TRAFICANT. That doesn't sound too good.

Dr. Spencer.

Dr. WEISS. That's why I drink wine in Washington. [Laughter.]

Mr. TRAFICANT. You wouldn't drink that wine, though, if you were working in an auto body spray shop, would you?

Dr. WEISS. That's right.

Dr. SPENCER. I guess there are two levels that I could respond to that important question.

First of all, many of the solvents that Dr. Weiss has referred to have acute effects, depressive effects on the nervous system, and the mixture of drinking and exposure to solvents of that type is likely to be additive, although detailed research in this area hasn't really been done. All those effects would be reversible, anyway.

On another level, chronic alcohol use is well known to induce a vitamin B1 deficiency state, which is also very much associated with a number of chemical substances which produce neurological disease, and, therefore, a priori one would argue that, yes, chronic exposure to alcohol sufficient to deprive the individual of—sufficient to drive thiamine balance down would be—would predispose the individual to those compounds which were acting through a similar mechanism.

It's not as easy—it's not easy enough or it's not possible to generalize to all chemical substances in the workplace. There are going to be some which work and some not. And one could also throw up an example of a compound which, in fact, is likely to reduce the amount of alcohol intake in an occupational compound, because if you happen to be a worker exposed to carbon disulfide, the last thing you want is a drink of alcohol because they don't mix well.

One of the drugs that one uses in clinical medicine to prevent alcohol abuse is a compound which might be working through a similar mechanism as carbon disulfide. It's a very complex question that you ask.

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Mr. TRAFICANT. That's in line with the point. Are there any safety precautions or any type of occupational directives to individuals that are highly exposed or working in fields, related fields, that have high incidence of exposure to these types of chemical problems, and it's possibly synergistic effects could be present with certain types of diet or lack of diet and/or abuse of substances, et cetera? I particularly feel that's one area that should be reviewed, and if it's not being tested or studied extensively, it should be pursued.

Another question I have is, naturally, along with any chemical abuse factor, the mode of administration becomes rather significant. Relative to the neuroingestion through the gastrointestinal tract or rather through the respiratory tract of high volatile spray contaminants, has there been a study to show that—is it mostly these types of problems that show the chronic abuse pattern or are there topical types of ingestion or are there other gastrointestinal tract types of ingestion that are just as significant? Or is it basically the spray volatiles that are the most significant?

That's more or less just a feeler question. I'd like some response from either.

Dr. SPENCER. Well, again, it's right on the money because I think in your own State, Congressman, in 1973 it was clearly demonstrated that concurrent exposure to methylethyl ketone and methylbutyl ketone was responsible for inducing partial paralysis among up to 70 workers, I believe. And it was shown at that time that—or shortly thereafter—in laboratory studies that the entrance of the neurotoxic entity methylbutyl ketone, a solvent, in fact was quite likely to be greater through skin, unbroken skin, than it was by lungs.

Of course, classically, in occupational health I suppose one has been most concerned about inhalation exposure to volatile agents, but—and, of course, on that basis, one is regulated with the introduction of threshhold limit values for airborne exposure over a working day.

What has been paid too little attention to is the possible absorption of very significant quantities via skin, and this is a serious practical problem for the worker in a hot, uncomfortable factory. The last thing he wants in terms of comfort, immediate comfort, is a mask around his face and long gloves on his hands. Some considerable attention needs to be paid to this factor in order to reduce the exposure of our skin.

Mr. TRAFICANT. Dr. Weiss.

Dr. WEISS. There have been accidents, in fact, due to, for example, methyl or wood alcohol running down through the pant leg into the shoe where it was absorbed through the skin, causing a severe episode of methyl alcohol poisoning. This is from the other solvents, too.

The reason they get through the skin is the same reason they get into the brain. They're taken up by fat. They pass into the circulation very readily.

Mr. TRAFICANT. I appreciate that. Maybe the last question is that I was a little bit late coming in here. Do either of the universities and your departments that you represent have current a research

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grant or project in operation that has been funded by the Congress here?

Dr. WEISS. Yes; both Dr. Spencer and I have centers. The University of Rochester has an Environmental Health Sciences Center funded through the National Institute of Environmental Health Sciences. The center itself is supposed to provide long-term support for salaries, faculty salaries, and also for the support of core units, core service units such as pathology, analytical chemistry, biostatistics, et cetera.

We have been trying—that is, the eight centers through the United States—through the past few years to have Congress provide more funding for the centers, which are capped at a million dollars a year, which means that we have to draw money for day-to-day maintenance from research grants.

Our research grants all come through peer review competitive applications, largely through NIH, and the reduction in real money for NIH has meant, of course, that our programs have been constricted over the past few years.

It also means a level of competition that for a younger faculty is very disheartening. Those of us who are tenured feel more secure. Those who are not feel sorely tempted to leave the whole academic research enterprise and give up in disgust.

In fact, our graduate students in toxicology almost universal now opt not for academic research, but for industry, because they see what the competition for research funds has done to their mentors.

Mr. TRAFICANT. That old supply side theory, you know, takes over in the environment——

Dr. WEISS. Yes; but who is going to replace us?

Mr. TRAFICANT. I know. That's what I'd just like to know for the record.

Dr. SPENCER. The universities in New York are also being decimated.

Mr. TRAFICANT. The bottom line is we have a growing problem, fewer and fewer dollars meaningfully directed toward the specific problem which we're discussing today; is that what you're saying?

Dr. WEISS. Yes.

Mr. TRAFICANT. Now like many people that might come before a committee, you're saying that the initiation of more dollars is going to readily reduce the threat that Americans face in the workplace? Is that our answer here?

Dr. WEISS. No; it's not the direct answer. We need to pay attention to the long-range implications of how we run our society. It's not the same as pumping money into the next accident.

The same problems that emerged under different administrations when we try for an immediate fix have also prompted the equivalent problems in research. We see a discharge of dioxin, and we rush to fix it. We see an accident like Bhopal or its equivalent, and we try to fix it.

What we're losing is what sustained science over the last four or five decades; that is, a base from which it could draw to deal with the problems of the society, a base of information, a base of knowledge.

It's not going to help if Congress throws money at us saying, "Fix it right now," because we have a problem with solvents, say. It will

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help if Congress decides that the scientific enterprise in this country needs sustained, long-term intelligent support.

Mr. TRAFICANT. I have no further questions, except to say that I would like to have any and all information you might have relative to the alcohol and/or drug abuse being already present in the workplace and the types of other problems that ensue to the American workers even though they're outside this specific field. You can send them to the committee. I would appreciate that personally.

Dr. WEISS. Well, there is a problem with solvent abuse. I'm not sure how much of that you encountered, but there was an article in a very well-known scientific journal entitled "Rolling Stone" some years ago about the vinyl chloride episode.

Mr. TRAFICANT. Yes.

Dr. WEISS. There it was pointed out that some of the workers would lean over into the vinyl chloride vats and get intoxicated, get high. It's a way of getting drunk on the job.

And the degree to which that recreational workplace behavior contributed to the angiosarcoma, the liver cancer, observed in these workers is totally unknown.

There was an article in this week's Journal of the American Medical Association in fact about solvent abuse. And, occasionally after lectures I've given on behavioral toxicology, chemists, and other people would come to me and say, "Yeah, we've seen it in our own workplace."

In fact, I think, there was a suit in Michigan from a woman who sued the company in which her husband was employed because he became dependent on sniffing toluene, the same solvent you find in airplane glues.

It's an underground problem that no one has been willing to face.

Do you have any experience with that?

Mr. CARSNER. Well, I do have some comments. I'd like to state, on the specifics, Rod Wolford could tell you. There was a study he was telling us about, the monkey—I say monkey studies. You've got another term for the type of animal, but it was the primate type. And now you can—I get the opinion that the drinker that goes into the plant that gets screwed up from the chemicals because he drinks, whereas I see from the studies and stuff that are being brought out now that what you're working with in the plant can cause you to have these urges for the alcohol, which is a solvent, as you know. Alcohol is a solvent. It's a drug, but it's a solvent—of the solvent family?

Dr. SPENCER. Yes.

Mr. CARSNER. OK. And so the problem here now, you're talking about the people—now I never intentionally indulged in any chemicals that I know of to be dangerous. I'm trying to make a broad spectrum here. I never went for glues or anything like this.

I have seen people walk up to water faucets—up to thinner faucets that look like water faucets, unless you had some experience, and drink from them.

I've seen other people—I have seen them sniff lacquer thinner cans. Now I'm not putting this blame on the worker because I've also seen and realized over a period of years that you're exposed to

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these chemicals, and these doctors will tell you it gives you this euphoric high. You do not intentionally go in there to get this chemical-induced high, but you become dependent upon it.

So when it's looked in the light of it was put in front of you, the proper equipment wasn't there, and you become addicted to it, you know, you can't say, "Well, gee, if guys would just straighten up their act, they wouldn't have the problem with the chemical."

One multiplies it. The monkey studies—the monkeys went for the—they were induced with solvents. I forget the particular type. And the two monkeys that were—there were four of them—two were isolated and separate. They put in a vial of water and a vial of alcohol, and they never had solvents or anything before. This set over here they induced solvents and the monkeys went—tried the water and the solvent and went for the solvent every time, chose it. These two over here that never—went for the water.

Mr. TRAFICANT. I'll yield back, and I think it's fair to say, though, that petroalcohol has seduced an awful lot of people. I wonder just what is the ramification of abuse, and any corelated study—that's the thrust of what I'm saying—relative to some of the problems we're looking at today.

Mr. VOLKMER. Thank you very much.

Before we close this panel, I would like to ask, because I think you pretty well touched on the question of what we can do as far as further research into this, but into that area, do you have any comments you'd like to make as to what categories or what types of chemicals perhaps we should be looking at in a priorities basis?

Dr. WEISS. From the standpoint of neurotoxicity——

Mr. VOLKMER. Yes, from the standpoint of neurotoxicity.

Dr. WEISS [continuing]. I think the dominant chemicals would be heavy metals, solvents, and allied chemical classes, insecticides, and I think, important but neglected, food additives.

Mr. VOLKMER. Dr. Spencer.

Dr. WEISS. Also, certain air pollutants.

Mr. VOLKMER. Air pollutants.

Dr. Spencer, do you have any comment?

Dr. SPENCER. I would support what Dr. Weiss has said. I wouldn't be so restrictive perhaps as to say insecticides, perhaps pesticides and fungicides, a broader category.

I would also add, because of my experience with regard to fragrance raw materials, that I strongly suspect the American public would like to know what is applied to their skin voluntarily, and I suspect that they would be very troubled to learn that for 50 and 30 years, respectively, agents have been applied to skin voluntarily, often under the guise that they are in fact improving skin quality, but are able to penetrate skin, and a recent experiment with animals caused devastating changes in the nervous system. So I would like to add fragrance raw materials, some of which are food additives as well, to that list that Dr. Weiss offered.

Mr. VOLKMER. Do you have any further comments, anybody?

[No response.]

Otherwise, we will conclude with this panel. I want to thank all of you for your testimony. It's been very informational and helpful. And with that, we'll conclude this panel.

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We may have additional questions after staff has reviewed this to send to you. If you do receive them, I'd appreciate your written responses as soon as possible.

With that, we'll conclude the first panel and we'll start with the second panel.

Our second panel shall be Dr. Don Clay, Director of Toxic Substances, Environmental Protection Agency; Dr. Donald McMillan, chairman, Department of Pharmacology, University of Arkansas, Little Rock; and, again, Dr. Spencer. You're still there. It's going to be a long morning for you.

In this panel we will discuss testing for neurotoxicity.

We will begin with Dr. Clay, and your testimony will be made a part of the record at your point in the record, and you may summarize or review it in full, however you so desire.

Dr. Clay.

STATEMENT OF DON R. CLAY, DIRECTOR, U.S. ENVIRONMENTAL PROTECTION AGENCY

Mr. CLAY. Thank you, Mr. Chairman.

I will summarize my statement and the whole thing can be in the record.

Let me clarify, I'm not a doctor; I'm just a Mr., before we get too far.

Mr. VOLKMER. Pardon?

Mr. CLAY. I'm not a doctor; I'm just a Mr.

Mr. VOLKMER. A mister?

Mr. CLAY. Yes, no doctor.

Mr. VOLKMER. Mr.?

Mr. CLAY. I am accompanied today by Dr. Bill Sette and Dr. Levine of my staff who will be getting into more detailed neurotoxicity questions.

Mr. VOLKMER. You don't have an honorary degree or anything like that?

Mr. CLAY. Masters of science and chemical engineering. That's the best I can do.

Mr. VOLKMER. Fine.

Mr. CLAY. Anyway, I am Don Clay, Director of the Office of Toxic Substances at EPA, and, as such, I am responsible for implementation of the Toxic Substances Control Act, or TSCA. I hope to use the time we have this morning to describe the work that we have done in the Office of Toxic Substances, OTS, to further development and use of neurotoxicity guidelines and testing.

Congress enacted the Toxic Substances Control Act, TSCA, in recognition of what was perceived to be loopholes among existing statutes that were limited in scope to specific health or environmental problems. Congress placed in TSCA sweeping authorities to collect both scientific and economic data about chemicals. These data were designed to build a centralized base of information to support sensible and effective chemical regulations.

While these authorities are sweeping, Congress did not intend that they be used in a vacuum. TSCA is a risk-balancing statute. It requires EPA to carefully consider the economic impacts of its decisions, including whether they unduly impede or create unnecessary

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barriers to technological innovation. Risk-benefit analysis is a complex and difficult process, but it is inherent in every decision made under TSCA.

TSCA has three major thrusts:

The development of information, including filling gaps in our knowledge about chemicals;

Control risks from chemicals already in our midst, the so-called existing chemical problem; and

Finally, the review of new chemicals before they are manufactured and restrict their use if necessary.

However, it is a notification program and not a registration program.

Neurotoxicity testing and assessment crosses over into each of these three areas, although our major focus has been under section 4 of TSCA, the Chemical Testing Program.

Chemical testing is a major source of data development for EPA. To require testing, EPA must first find that the chemical substance either may present an unreasonable risk or it is or will be produced in substantial quantities and is handled in a manner that may result in substantial environmental release or human exposure.

Second, EPA must find that the data are insufficient to evaluate the chemical and that testing is necessary to develop data concerning potential adverse effects.

The extent of the need for testing of industrial chemicals has recently been emphasized by a National Academy of Sciences study that I am sure Dr. McMillan will cover in more detail shortly.

While it is difficult to estimate the magnitude of the neurotoxicity as a problem, the Office of Toxic Substances recognizes that neurotoxic effects are sufficiently prevalent to warrant an important emphasis. There are over 850 known neurotoxic chemicals, as pointed out by Anger & Johnson.

On September 27 of this year the Office of Toxic Substances published the latest set of health effects test guidelines, including 48 in number, in the Federal Register, including 8 guidelines for neurotoxicity studies in animals. These were published as convenience to the neurotoxic ones that actually had been published earlier in the 1981–82 timeframe. Each of these guidelines is reviewed by experts in academia, Government, and industry.

The selection of the neurotoxicity guidelines was based on recommendations of various committees of the National Academy of Sciences, their widespread use in the neurotoxicology community, and the OTS perception of the most basic testing needed for identification and characterization of potential neurotoxicants.

For specific needs for which guidelines are not available, they must still be developed on a case-by-case basis.

The estimated cost of testing conducted under the guidelines ranges from $2,000 for the neurotoxic esterase assay to $100,000 for a subchronic neuropathology study. The bulk of the higher costs are for conducting any subchronic study in the $50,000-to-$60,000 range; the incremental costs for adding specific testing to such a study range from $5,000 to $40,000.

We have asked for neurotoxicity testing on several new and existing test rule chemicals. Of the final three test rules, one of them

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requires neurotoxicity testing. Of the 22 proposed test rules, 6 of them include neurotoxicity testing requirements. In two cases manufacturers are conducting voluntary testing for neurotoxicity as the result of negotiations with the Office of Toxic Substances. Of the eight advance notices of proposed rulemaking, six discuss the need for neurotoxicity testing and request public comment on the proposed testing.

In the last 7 years our new chemicals program has reviewed over 5,000 chemicals for all types of health and environmental effects. Approximately 12 to 16 percent of these chemicals generate sufficient health or environmental concerns to require more detailed review. Over 120 detailed reviews for neurotoxicity concerns have been conducted, and there has also been a total of 69 orders regulating exposure pending the development of test data.

Potential neurotoxic hazards have been identified in consent orders for 15 chemicals, and voluntary testing for neurotoxicity has been conducted on 6 new chemicals.

In summary, OTS has recognized and continues to recognize that neurotoxic effects warrant important emphasis. We believe we have the most complete and state-of-the-art guidelines for neurotoxicity evaluation in the regulatory arena today. We have used these guidelines to obtain data on a variety of new and existing chemicals. Our neurotoxicologists are working with other regulatory agencies and in the International OECD to improve the extent and quality of neurotoxicity testing within the broader context of chemical regulation.

Mr. Chairman, I appreciate this opportunity to provide the subcommittee with this statement. And at the appropriate time, I will be pleased to answer any questions you may have.

Thank you.

[The prepared statement of Mr. Clay follows:]

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STATEMENT OF
DON R. CLAY, DIRECTOR
OFFICE OF TOXIC SUBSTANCES
U. S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE OF SCIENCE AND TECHNOLOGY
HOUSE OF REPRESENTATIVES

OCTOBER 8, 1985

Mr. Chairman, members of the Subcommittee; Good morning. I hope to use the time we have this morning to describe the work that we have done in the Office of Toxic Substances (OTS) to further the development and use of neurotoxicity guidelines and testing.

Background

Congress enacted the Toxic Substances Control Act (TSCA) in recognition of what was perceived to be loopholes among existing statutes that were limited in scope to a specific health or environmental problem. There was concern that new chemicals could be manufactured and enter the environment without any government review of potential harmful effects. There were concerns that existing chemicals were not being tested or that they were not covered by existing authorities. Congress placed in TSCA sweeping authorities to collect both scientific and economic data about chemicals. These data, Congress hoped, would begin to build a centralized base of information to support sensible and effective chemical regulations.

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While these authorities are sweeping, Congress did not intend that they be used in a vacuum. TSCA is a risk-balancing statute. It requires EPA to carefully consider the economic impacts of its decisions, including whether they unduly impede or create unnecessary barriers to technological innovation. Risk/benefit analysis is a complex and difficult process, but it is inherent in every decision made under TSCA.

TSCA has three major thrusts:

- Develop information - filling gaps in our knowledge;
- Control risks from chemicals already in our midst, "existing chemicals"; and
- Review new chemicals before they are manufactured and restrict their use if necessary.

Neurotoxicity testing and assessment crosses over into each of these three areas, although our major focus has been under section 4 of TSCA- the Chemical Testing Program.

Chemical testing is a major source of data development for EPA and authority to require such testing is embodied in Section 4 of TSCA. To require testing, EPA must first find that the chemical substance either may present an unreasonable risk or it is or will be produced in substantial quantities and is handled in a manner that may result in substantial environmental release

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or human exposure. Second, EPA must find that data are insufficient to evaluate the chemical and that, third, testing is necessary to develop data concerning potential adverse effects.

Neurotoxicity Testing

The extent of the need for testing of industrial chemicals has recently been emphasized by a National Academy of Sciences (NAS) Study that assessed the toxicity-testing needs for substances for which there is known or anticipated human exposure. The NAS group identified a select universe of chemicals consisting of a wide variety of those used in commerce, food additives, cosmetic ingredients, and pesticides and inert ingredients. A set of test guidelines was established against which to determine the adequacy of existing toxicity evaluation. The guidelines for neurobehavioral toxicity, which is the adverse effect of a chemical on the way an animal behaves (moves, sees, hears, feels, learns) and on the cells in the nervous system, included neuropathologic evaluation, and functional evaluation of both learned and unlearned behavior. Neurobehavioral toxicity was the area of greatest testing need in two categories: pesticides and inert ingredients in pesticide formulations, and cosmetic ingredients. For food additives and for three separate categories of chemicals in commerce, neurobehavioral toxicity evaluation ranked in the top five areas of greatest testing need.

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While it is difficult to estimate the magnitude of neurotoxicity as a problem, the Office of Toxic Substances recognizes that neurotoxic effects are sufficiently prevalent to warrant an important emphasis. There are over 850 known neurotoxic chemicals as pointed out by Anger and Johnson (1985). Of the 588 Threshold Limit Values (TLVs) recommended by the American Conference of Government Industrial Hygienists (ACGIH), 167 of them (28%) are based in whole or part on neurotoxic effects (Anger, 1984). The National Institute of Occupational Safety and Health (NIOSH) has recommended workplace standards for 35 chemicals based partly or entirely on their neurotoxic properties (Fisher, 1980) and estimates that over 20 million workers are exposed to at least one known neurotoxic chemical (Tilson and Mitchell, 1984). NIOSH also recognizes neurotoxic and psychologic effects as two of the ten leading workplace disorders (NIOSH, 1984).

On September 27, the Office of Toxic Substances published the latest set of health effects test guidelines (48) in the Federal Register, including eight guidelines for neurotoxicity studies in animals. Although these guidelines have been developed for the purpose of testing existing chemicals under Section 4, they also serve as the basis for testing recommendations of new industrial chemicals under Section 5 as well. Each guideline was reviewed by experts in academia, government, and industry. Members of the Office of Research and Development at EPA contributed to the development of several

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guidelines. Selection of the neurotoxicity guidelines was based on recommendations of various committees of the National Academy of Sciences, their widespread use in the neurotoxicology community, and OTS perception of the most basic testing needed for identification and characterization of potential neurotoxicants. Generally, the neurotoxicity guidelines are designed so that a test will be able to identify neurotoxic effects of particular concern. For example, one of the most common neurotoxic effects is paralysis. We have several tests to evaluate paralysis. Some tests identify chemicals which can produce paralysis; some are used to precisely define early signs of paralysis. However, it should be noted that the large variety of potential neurotoxic effects make an exhaustive set of guidelines an impossible task. For specific needs for which guidelines are not available, they must be developed on a case by case basis.

The eight guidelines consist of:

- a neuropathology guideline for describing effects on the structure of cells in the nervous system;
- a functional observational battery that is a simple neurological examination of the rat;
- motor activity and operant (learned) behavior guidelines to measure unlearned and learned behavior;
- a guideline for studying the function of a peripheral nerve with mild electrical stimulation;

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* and 3 guidelines to identify the effects of organophosphates on walking ability, the structure of nerve cells, and changes in the chemistry of those cells.

Of these eight guidelines, two that evaluate organophosphates were developed by the Organization of Economic Cooperation and Development and have been adopted by the international community as well as the Office of Pesticides Programs.

The estimated cost of testing conducted under the guidelines ranges from $2,000 for the neurotoxic esterase assay to $100,000 for a subchronic neuropathology study. The bulk of the higher costs are for conducting any subchronic study ($50-60,000); the incremental costs for adding specific testing to such a study range from $5,000 to $40,000.

We have asked for neurotoxicity testing on several new and existing test rule chemicals. Of the three final test rules, one of them, on the C-9 fraction of gasoline (ethyl toluene, and trimethyl benzenes), requires neurotoxicity testing. Of the 22 proposed test rules, six of them, those for cumene, 2-mercaptobenzothiazole, cresols, dichloropropane, hydroquinone, and oleylamine include neurotoxicity testing requirements. In two cases, propylene oxide and cyclohexanone, manufacturers are conducting voluntary testing for neurotoxicity as the result of

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negotiation with OTS. Of the eight advance notices of proposed rulemaking, six discuss the need for neurotoxicity testing and request public comment on the proposed testing.

In the last seven years, our new chemicals program has reviewed over 5700 chemicals for all types of health and environmental effects. Approximately 12-16% of these chemicals generate sufficient health effects concern to require more detailed review. Over 120 detailed reviews for neurotoxic concerns have been conducted. There have been a total of 69 5(e) consent orders (on a total of 113 chemicals) regulating exposure pending or in lieu of the development of test data. For 12 of these 5(e) orders, testing will be required when the production volume reaches a certain level. Potential neurotoxic hazards have been identified in consent orders for 15 chemicals which were the subjects of 11 5(e) orders. Three of these orders on 4 new chemicals have testing triggers for neurotoxicity. Voluntary testing for neurotoxicity has been conducted on 6 new chemicals.

In summary, OTS has recognized and continues to recognize that neurotoxic effects warrant important emphasis. We have the most complete and state-of-the-art guidelines for neurotoxicity evaluation in the regulatory arena today. We have used these guidelines to obtain data on a variety of new and existing chemicals. Finally, our neurotoxicologists are working with other regulatory agencies and the OECD to improve the extent and quality of neurotoxicity testing within the broader context of chemical regulation.

Mr. Chairman, I appreciate this opportunity to provide the Subcommittee with this statement. I will be pleased to answer any questions you may have.

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Mr. VOLKMER. Thank you very much, Mr. Clay.
Dr. McMillan.

STATEMENT OF DR. DONALD E. McMILLAN, CHAIRMAN, DEPARTMENT OF PHARMACOLOGY, UNIVERSITY OF ARKANSAS AT LITTLE ROCK, LITTLE ROCK, AR

Dr. MCMILLAN. Thank you, Mr. Chairman, ladies and gentlemen.

As Mr. Clay has stated, there are approximately 8 million known chemicals. Recently, a select committee of the National Academy of Sciences identified somewhere in excess of 50,000 of those chemicals where human exposure is likely. This number does not include any natural products, which may also have effects on human behavior, nor does it include any one of the tremendously large number of mixtures of chemical compounds.

The academy group suggested that almost nothing is known about the neurobehavioral toxicity of this group of chemicals. Probably less than 1 in 100 have been adequately tested.

To support this statement, I ask that you turn to page 5 of my testimony to table 1, which outlines the findings of this National Academy committee, which has been published within the last year in a document entitled "Toxicity Testing: Strategies To Determine Needs and Priorities."

If you look at that table, you can see that pesticides, cosmetics, drugs, food additives, and chemicals in commerce, those with over 1 million pounds manufactured annually, those with less than 1 million pounds manufactured annually, and those where the amount manufactured annually is unknown, have been categorized as to being the intended use of these chemicals.

If you look at the second column of this table, this gives you the percentages of each of these intended uses where there has been no testing done, after a complete search of the available literature.

You can see that in the sample that the Academy surveyed of 100 chemicals, no testing had been done whatsoever on a number of chemicals in commerce. If you look at the third column, this shows you the percentage of tests done that were judged by the select committee to be inadequate when some testing did appear in the literature. Again, you can see that when the testing has been done for neurobehavioral toxicity, in many cases the committee judged this testing to be inadequate to establish whether or not neurobehavioral toxicity was a serious problem.

Why does this situation exist? Why do we know so little about neurobehavioral toxicity testing? The most frequent reason, or excuse rather, is that we don't have adequate test methods, especially for behavioral toxicity. I think this is simply not the case.

Several National Academy of Science committees, groups of EPA scientists, the committee of the American Psychological Association, and many other groups have recommended test standards that overlap to a large degree. If we had the national will, we could begin to do such testing immediately.

Would it be successful? Again, let's take, for example, the National Academy of Sciences' toxicity testing strategies to determine needs and priorities and look at what this group has recommended. They recommend three general types of tests:

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First, neuropathology. I think it goes without saying that if a particular chemical is eating holes in our brain that this is an undesirable effect and that this chemical should undergo some sort of regulation.

Two types of behavioral measures were recommended. First is unlearned behavior, general patterns of motor activity over 24-hour periods: do the animals' daily routine of life change as a function of exposure to the chemical?

Second, learned behavior. Can the animal learn the new behaviors that will allow him to adapt? Will he be able to respond to changes in his environment that allow him to survive?

A simple three-pronged screen like this would, in my opinion, detect all of the known neurotoxins, those that we currently are sure are causing problems in man. There is no reason to think that such screens would not pick up the neurotoxins that we do not currently know about.

Will there be false positives? Will we make some mistakes? After all, how accurately can a rat's behavior predict the subtle effects on human behavior, humans who have language, who can read, who can write, who can do many things that a rat cannot?

I don't think the extrapolation in terms of neurobehavioral effects is any different problem than it is in terms of any other kind of toxicity testing where we must rely on an animal model and then extrapolate to the humans.

Look at the saccharin controversy, for example. The press inundated us with estimates of how many swimming pools full of saccharin people would need to drink in order to reach the same level of exposure that the rats had had in these studies.

Neurobehavioral toxicity will have the same kinds of extrapolation problems. There is no evidence that they will be any more or any less difficult than in other fields.

As research progresses, we'll get better than we are, but I think we're pretty good right now. We have tests that can protect the public health. All we need is the decision to put them in place.

[The prepared statement of Dr. McMillan follows:]

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PREPARED STATEMENT OF DONALD E. MCMILLAN

In September of 1980, the National Toxicology Program, through the National Institute of Environmental Health Sciences, contracted with the National Academy of Sciences for a report to characterize the toxicity testing needs for chemicals to which there is known or anticipated human exposure and to develop priorities for research on chemicals with potentially adverse effects for human health. The first part of this charge required a detailed examination of existing toxicity data. This was no small task as there are about 5 million known chemicals; however, a committee of the National Research Council defined a number of about 53,000 distinct chemicals to which human exposure is likely in the form of pesticides, drugs, food additives, cosmetics and chemicals in commerce. This "select universe" of chemicals does not include natural products, environmental decomposition products, manufacturing contaminants or chemical mixtures, which also may constitute a threat to human health.

The Committee on Toxicity Data Elements, which was the National Research Council Committee charged with the review of this toxicity information, obviously could not begin to review the toxicity data on more than 53,000 chemicals. Therefore, a random sample of 675 substances was selected from the original listing and a random stratified subsample of 100 chemicals with at least minimal toxicity information was selected for detailed study as outlined in Figure 1 which is from the National Academy of Science report (1). Using this sampling procedure, it is possible to make inferences about the "select universe" from the sample.

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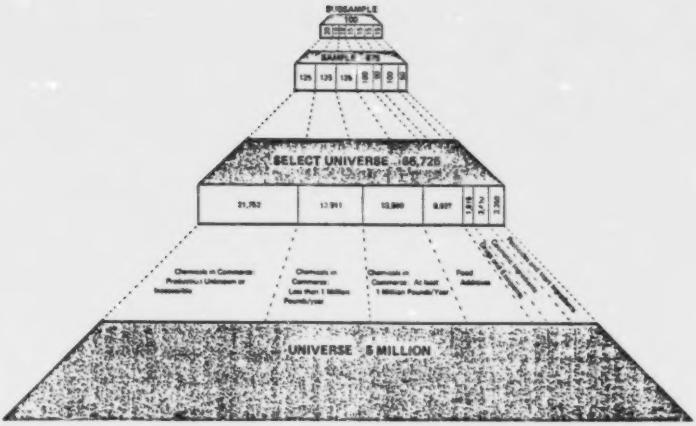

FIGURE 1 Content and size of each category of substances in the select universe, sample, and subsample.

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On the basis of its expertise, the Committee on Toxicity Data Elements developed a consensus as to what kinds of toxicity testing were needed to make a health-hazard assessment for chemicals in each exposure class (e.g., pesticides, cosmetics, etc.) and what types of research protocols could best provide research data of sufficient quality that a health-hazard assessment was possible. For most types of toxicity testing the Organization for Economic Co-operation and Development Guidelines for the Testing of Chemicals (2) was used as the source of protocols used to evaluate the adequacy of toxicity testing. Neurobehavioral toxicology testing, however, was one of several areas where these Guidelines were judged to be inadequate, so the Committee developed its own guidelines for neurobehavioral toxicity testing relying heavily on the recommendations of a previous National Research Council Committee that developed behavioral toxicity testing protocols (3) and on currently accepted methods for measuring neuropathology (4). The protocol guidelines for neurobehavioral-toxicity testing developed by the Committee on Toxicity Data Elements are appended to this report.

When the adequacy of testing for neurobehavioral toxicity was evaluated according to the guidelines developed by the Committee, neurobehavioral toxicity consistently fell at the top, or very near to the top, of the list of testing needs for each chemical category (Table 1). Of the 100 chemicals in the sample, 93 had absolutely no neurobehavioral testing reported in the open literature and 6 had received inadequate neurobehavioral testing. Only one chemical was considered to have received testing adequate to determine if it produced sufficient neurobehavioral toxicity to be a human health hazard. If the sample data can be extrapolated to the select universe of chemicals, it suggests that very little neurobehavioral testing is being done and that what

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little amount that is being done is not adequate to evaluate the human health hazards of chemicals.

TABLE 1: Testing Needs for Neurobehavioral Toxicity by Use Category (as percentage of select universe).

Intended Use	Percentage with No Testing Done	Percentage of tests done that were judged inadequate
Pesticide	67	100
Cosmetic	100	-
Drug	47	88
Food Additives	73	100
Chemicals in Commerce		
> 1 million lbs	100	-
< 1 million lbs	90	100
Unknown	100	-

Why is neurobehavioral toxicity testing of chemicals so rarely done? An argument frequently advanced is that the methods for such testing are not available, or at least are not generally agreed upon. This is simply not true. Although the various groups that have recommended protocols for neurobehavioral testing have developed protocols that differ in detail, there is a great deal of similarity among most of them. Almost all of such protocols require the measurement of simple behaviors and/or neuropathological examination. A protocol such as that developed by the Committee on Toxicity Data Elements and appended to this report should detect all currently known neurotoxins and psychoactive chemicals. There is no reason to believe that this protocol would

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not be a sensitive test for the potential neurobehavioral toxicity of untested chemicals. The reasons for inadequate neurobehavioral testing of chemicals that may have adverse health effects relates to economic factors and political decisions, not to inadequacies of the test methods.

References:

1. National Research Council. Toxicity Testing: Strategies to Determine Needs and Priorities. Washington, D.C., 379 pp (1984).

2. Organization for Economic Co-operation and Development. Guidelines for the Testing of Chemicals. Paris, 700 pp (1981).

3. National Research Council. Principles and Procedures for Evaluating the Toxicity of Household Substances. Washington, D.C., pp. 111-118 (1977).

4. Spencer, P.S. and Schaumburg, H.H. Experimental and Clinical Neurotoxicology. Baltimore, 829 pp (1980).

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APPENDIX I

REFERENCE PROTOCOL GUIDELINES FOR NEUROBEHAVIORAL-TOXICITY TESTS

Neurobehavioral-toxicity testing requires both morphologic and behavioral assessment. With current methods, the effects of some chemicals are most reliably detected by measuring morphologic changes, whereas other chemicals produce behavioral changes without, as yet, the identification of any morphologic basis. Because methods for neurobehavioral-toxicity testing are still being developed and validated, a high degree of standardization in such testing is inappropriate at this time. Nevertheless, a scheme proposed by a committee of the National Research Council (1977) gave specific and detailed suggestions of protocols for neurobehavioral-toxicity testing. The scheme, presented here, is a reasonable starting point for neurobehavioral-toxicity testing, and the suggested protocols were used as the reference protocol guideline in this study.

The 1977 committee recommended that both conditioned and unconditioned behaviors be studied. For unconditioned behavior, it suggested that circadian patterns of spontaneous motor activity (SMA)* be measured. SMA in rodents has been widely studied to document behavioral changes produced by chemicals.

This procedure does not require any special training of personnel. For conditioned behavior, it suggested that performance maintained by schedules of food presentation be used as a measure. Some types of schedule-controlled responding** require little training of the animal, but provide an estimate of the effects of a substance on fairly complex behavioral processes. Reiter et al. (1981) have found that measurements

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* Spontaneous motor activity (SMA) is a measurement of an animal's body movement under a given set of environmental conditions. SMA may be detected by a variety of techniques, including photocell-beam interruption and changes in a capacitance field. It is important that measurements be objective and unbiased. Use of automatic instrumentation is recommended for the measurement of SMA.

** Schedule-controlled responding is maintained by reinforcement. For example, animals are trained to make specific responses to specific stimuli to obtain food or water or to avoid shock. The relationship of the response to delivery of such reinforcers is called the schedule of reinforcement, and the behavior may be referred to as schedule-controlled responding (Ferster and Skinner, 1957).

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of SMA and schedule-controlled behavior are two of the most sensitive tests for determining the behavioral effects of pesticides. A battery of sophisticated techniques for more detailed evaluation of substances for neurobehavioral effects is gradually being developed (Geller et al., 1979).

Measurement of morphologic changes in the nervous system requires in situ perfusion of the animal and the use of contemporary methods of nervous system preparation for examination by light microscopy and perhaps electron microscopy. Spencer et al. (1980) have developed procedures for tissue preparation based on glutaraldehyde fixation that permit classification of neurotoxins according to their target sites (e.g., soma and myelin). Their system permits assessment of the location, type, and degree of neurotoxic damage. For the neurotoxins studied thus far, there is a good correlation between the type of neurotoxic damage observed in animal models and the type of neurotoxic damage produced by the same substances in humans.

In addition to the behavioral and morphologic testing recommended for the screening of neurotoxins, a host of other approaches to neurotoxicity testing are under development. Among these are tests involving tissue cultures, electrophysiology, and neurochemistry. The current stage of development of some of these approaches has been outlined briefly by Spencer et al. (1980).

PRINCIPLES AND DESCRIPTION OF TESTING FOR NEUROBEHAVIORAL EFFECTS

Many substances damage the nervous system (Spencer and Schaumburg, 1980) and thereby produce a variety of behavioral changes. Although no substance or series of substances can now be recommended as a reference for neurotoxicity testing, positive controls are always desirable. Agents with established neurobehavioral toxicity should be tested repeatedly to establish the sensitivity of the measurement system when new substances with potential neurobehavioral toxicity are under investigation.

A range of doses of a substance should be administered for acute-toxicity testing of neurobehavioral effects, including doses large enough to produce obvious effects. Fractions of the LD_{50} should be used, and the substances should be administered by the route of likely human exposure. Effects of the substances on SMA and schedule-controlled behavior should then be determined. Later, the animals should be sacrificed for histologic examination by light microscopy and possibly electron microscopy. For subchronic studies, three doses, including the highest dose that did not affect behavior or produce morphologic changes on acute administration, should be administered repeatedly.

Healthy adult animals should be randomly assigned to treatment and control groups. In some instances, behavior is exceedingly stable, and pre-exposure behavior provides control observations for the exposure period. Rats are the preferred animal, although mice are also appropriate. Standard breeds and strains should be used, and at least six animals should be studied at each dose.

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SMA must be measured under carefully controlled conditions (National Research Council, 1977). For example, strain of animal, feeding and watering schedules, time of day of testing, and conditions of temperature, humidity, and lighting must be specified. The device used to measure SMA must also be described in detail, although no particular method has yet been recommended.

For measurement of schedule-controlled responding, conditions must also be specified in detail. Again, the species, body weight, feeding and watering schedules, etc., must be specified. The reinforcement schedule should be described in sufficient detail to allow others to repeat the experiment under nearly identical conditions.

A reasonable time should be allowed to elapse, after the substance is administered, for absorption and distribution before behavior is measured. Animals should be tested daily for at least 1 wk after acute administration to determine the consequences of delayed neurotoxicity, such as that observed with alkyl tin compounds. Similar principles should be followed for subchronic testing. Where possible, it is desirable to have histologic examinations and behavioral testing of the same animals.

Additional animals exposed to the substance, but not tested for behavioral effects, can be added to the design as necessary to increase group size for time-response effects. Methods similar to those described by Spencer et al. (1980) are appropriate.

Tests of statistical significance should be applied to the data. Reproductions of histologic slides can often be used to illustrate types of neurotoxicity, although tables are generally necessary to document the frequency with which the illustrated events occurred. Specificity of neurobehavioral toxicity may be expressed as the ratio of the LD_{50} to the neurobehaviorally toxic dose. Neurobehavioral-toxicity evaluation and its relative importance should include a comparison with other toxicity data on the substance. For example, neurotoxic effects manifested only by a dose 10 times higher than that required for carcinogenicity would be of little regulatory interest.

The test report should include dose-effect data for behavior and morphology, a description of the location and type of neural lesions, the time course of the development of behavioral and morphologic changes, statistical treatment of the results, and an indication of the degree to which the toxicity is reversible.

Detection of either morphologic changes or behavioral changes caused by effects on the central nervous system can be considered as evidence of neurobehavioral toxicity that may be extrapolated to humans. The degree to which such extrapolation is valid is under investigation. More sophisticated understanding of specific types of behavioral toxicity would require a series of tests that is beyond the present protocol. When morphologic changes have been observed, the selection of later behavioral tests should be strongly influenced by the type, degree, and location of the morphologic changes.

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DETERMINATION OF ADEQUACY OF NEUROBEHAVIORAL-TOXICITY TESTING

Because no reference protocol guidelines for neurobehavioral-toxicity testing have been established and because much evidence of neurobehavioral toxicity exists in qualitative descriptions of the adverse effects of substances, the Committee on Toxicity Data Elements has established a series of criteria for judging the adequacy of neurobehavioral-toxicity testing, including observations of effects.

The neurobehavioral-toxicity data base (see Figure I-1) should contain studies on function (both conditioned and unconditioned behavior) and morphology (neuropathology). The committee regarded neurobehavioral-toxicity testing to be (1) adequate, according to reference protocol guidelines, only if all three study types followed the procedures described here; (2) adequate, but not according to reference protocol guidelines, if all three study types were conducted adequately, but not according to the procedures described here; and (3) inadequate if at least one of the three study types was missing or was conducted inadequately. The need to repeat studies conducted inadequately depends on the amount and quality of existing neurobehavioral-toxicity information on a substance. For example, documentation of extensive neural lesions (a morphologic response) might make behavioral testing (a functional response) unnecessary for regulatory purposes, because the neuropathologic effects already constitute a hazard. These criteria allowed the committee to determine whether neurobehavioral effects were observed with adequate or inadequate procedures.

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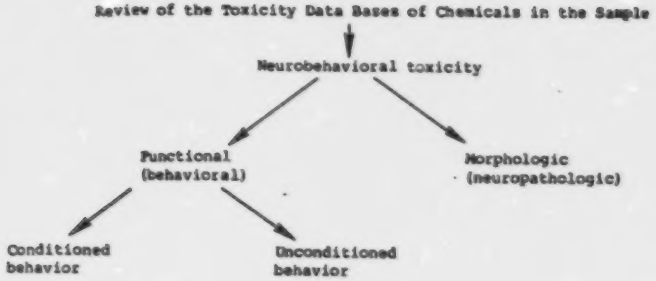

FIGURE I-1 Studies necessary for judging adequacy of neurobehavioral-toxicity testing.

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Mr. VOLKMER. Dr. Spencer.

STATEMENT OF DR. PETER S. SPENCER, DIRECTOR, INSTITUTE OF NEUROTOXICOLOGY, ALBERT EINSTEIN COLLEGE OF MEDICINE, BRONX, NY

Dr. SPENCER. Mr. Chairman, I'd like to begin my testimony by quoting from a recent scientific article reporting the outbreak of the toxicity that I referred to earlier in Lancaster, TX. And I'm quoting:

> The tragic lesson of this epidemic is that it could have been prevented by adequate premarket evaluation of BHMH. Premarket testing is the most effective means of assessing the toxicity of new chemical compounds. However, until the passage of TSCA in 1976, there was no legal mechanism in the United States for prospective evaluation of the neurotoxicity of new industrial compounds. Even since the passage of TSCA, inadequacies in testing requirements remain. Many thousands of potentially neurotoxic compunds whose introduction to commerce antedated passage of the act remain untested, and there are no requirements at present for testing such compounds; these compounds, BHMH among them, were simply registered with the EPA and were added by the EPA to the TSCA inventory. Also, testing procedures for new industrial compounds have not been standardized; responsibility for deciding whether or not to test a new chemical and for development of testing protocols is left almost entirely to the discretion of chemical manufacturers. Governmental review of the toxic potential of new chemicals consists typically of examination of their structural formulae.
>
> Although testing of BHMH for acute toxicity demonstrated ataxia, tremors, and possible convulsions in exposed rats, the manufacturer apparently did not consider the compound to be neurotoxic on the basis of these results and did not warn users of the potential neurotoxicity.

Also, as I said this morning—

> No chronic testing of the compound was performed.

How do we determine whether a chemical substance has the likelihood of having an adverse effect on the human nervous system, and what new methods might become available that would serve to reduce the cost and the number of animals used in these types of experimental evaluation?

The present procedures of neurotoxicity evaluation essentially rely on the use of selected laboratory animals. The chicken has proven especially suitable to assess one class of neurotoxic agents, but the rodent and dog are most commonly employed to study compounds with unknown effects. Primates are rarely used, although they represent invaluable experimental subjects to model some types of human neurotoxicity that are difficult to recognize in a lower species. Two or three species of small laboratory animals may be required to detect neurotoxicity since one or more may be relatively refractory to the chemical substance under study.

In an attempt to surmount this problem, toxicologists employ a range of doses of the test chemical, some of which may exceed the expected level of human exposure while others approach an environmentally significant dose. The numbers of animals required for neurotoxicity testing are much smaller than those needed to evaluate a chemical for carcinogenicity.

Young adult animals are normally used, unless questions pertaining to fetal toxicity or neuroteratogenesis are being addressed when pregnant dams form the subjects of study. Newborn animals have been used to investigate the neurotoxic properties of certain

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food additives and to model the action of chemical substances on the developing brain.

Test compounds are administered in known purity, varied doses, and for varying periods of time: a few days, so-called acute study; 90 days, the subchronic study; or throughout life, a chronic study.

Acute toxicity studies are highly relevant for predicting the effects of sudden human poisoning or of massive overexposure in an industrial setting. The subchronic animal studies have been employed to identify a number of neurotoxic substances, although negative results should be interpreted with caution since the additive effects of repeated exposure to low levels of neurotoxic agents may only be expressed after treatment periods longer than 90 days. Lifetime exposure is rarely used.

Now such studies, lifetime exposure, are routinely carried out in cancer bioassays but, as I mentioned, sample animals used in these extraordinarily expensive experiments have not been available to determine with sensitive methods whether the nervous system is also a target of chemical attack.

There are many other methods to evaluate alterations in the nervous system of animals exposed to chemical substances with neurotoxic potential. Sometimes the changes are obvious to the naked eye, appearing in the form of convulsions, tremor, urinary incontinence, or paralysis. On other occasions, the response is more subtle and may require a battery of functional tests or neurological examination to detect a change in neurobehavioral status.

Once a functional abnormality has been found, it requires further investigation by electrophysiological or morphological techniques to identify the site and nature of the chemical-induced change. A contemporary pathological examination is critically important to demonstrate the type of lesion and to assess whether it is likely to reverse if the chemical is withdrawn. Few chemicals with human neurotoxic potential would be missed in subchronic studies of a range of doses in two animal species examined by simple neurobehavioral and morphological methods. And such protocols for these methods will shortly be made available by the WHO.

However, while there is a clear need to subject existing and new chemicals to neurotoxicity testing, the backlog and future inventory of chemical substances would rapidly swamp the Nation's capacity both in terms of available laboratories and personnel. We must provide more support for those academic and other centers that are struggling to develop or maintain a program of investigation into chemical neurotoxicity.

Additionally, we must train more scientists in neurotoxicology as a subject that combines a solid understanding of the principles of neurobiology and toxicology.

Finally, we must sensitize medical students and physicians to the increasing frequency of neurotoxic disease and encourage them to search the patient's history for possible cause-and-effect associations.

Another important area for future endeavor is the development of more rapid methods to detect chemicals with neurotoxic properties. While the experimental animal will remain a cornerstone in

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the assessment of chemical neurotoxicity, other less expensive methods might serve to flag substances for future investigation.

One technique is to compare the chemical structure of the agent in question with that of a known neurotoxic chemical. This deceptively simple method presently is only useful for certain classes of substances because of our limited knowledge of structure-toxicity relationships and the ability of some chemicals to change their form in the body from a relatively innocuous material to a potent neurotoxin.

Much more work on mechanisms of chemical neurotoxicity will be required before structure-toxicity considerations prove generally useful as a screen for neurotoxicity. Other test methods now under development include the use of nonmammalian species and tissue-culture models of the nervous system. Both will likely prove useful for the initial detection of chemical neurotoxicity and to determine mechanisms of neurotoxic action. Once these are understood, mechanisms are understood at the biochemical level, it might be possible to devise rapid test tube assays to screen chemical agents for neurotoxic potential. Tests of this type are already available for one class of neurotoxic agents.

Finally, while increased neurotoxicology research and testing will lead to reduction and improved control of environmental and occupational neurotoxic substances, there are other hidden benefits in promoting this area of scientific endeavor.

As I mentioned, neurological scientists are realizing that chemical substances with neurotoxic potential are useful probes to explore the normal nervous system and to model in animals some of those neurological diseases which afflict mankind.

Two examples illustrate the point: MPTP, a contaminant of a synthetic heroin that induced a Parkinsonianlike disorder in Californian drug addicts, has caused a revolution in our understanding of the possible causes of Parkinson's disease by allowing neuroscientists to reproduce a similar disease in laboratory animals. Similarly, BOAA, a natural neurotoxin present in foodstuffs that have crippled hundreds of thousands of people in certain developing countries holds promise as a tool to investigate Lou Gehrig's disease.

In conclusion, there is a clear need to test existing and new chemicals for neurotoxic potential. Methods for neurotoxicity assessment are well established but expensive. Cheaper methods will only be developed if we increase our understanding of the biological mechanisms underlying the many types of chemical neurotoxicity. Research and training budgets for neuroscience-based neurotoxicology must be increased if this goal is to be realized. And a spinoff from this effort will be an increased understanding of major neurological diseases whose cause and prevention may thereby be established.

Thank you very much.

[The prepared statement of Dr. Spencer follows:]

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U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE AND TECHNOLOGY
SUB-COMMITTEE ON INVESTIGATIONS AND OVERSIGHT

HEARING ON NEUROTOXINS
OCTOBER 8-9, 1985

October 8 Afternoon Testimony of Peter S. Spencer, Ph.D., M.R.C.Path.

DETECTING THE THREAT AND USING THE TOOL

My name is Peter S. Spencer, and I am a U.S. citizen residing in New York State. My professional affiliation is with the Albert Einstein College of Medicine where I am Professor of Neuroscience and Director of the Institute of Neurotoxicology. After receiving my baccalaureate and doctoral degrees from the University of London, I joined my present institution where, for the past 14 years, I have been a full-time research scientist investigating the actions of chemical substances on the nervous system.

I begin my testimony by quoting from a recent scientific article (1) reporting the outbreak of BHMH neurotoxicity that I described this morning:

> "The tragic lesson of this epidemic is that it could have been prevented by adequate premarket evaluation of BHMH. Premarket testing is the most effective means of assessing the toxicity of new chemical compounds. However, until passage of the Toxic Substances Control Act (TSCA) in 1976, there was no legal mechanism in the United States for prospective evaluation of the neurotoxicity of new industrial compounds. Even since the passage of TSCA, inadequacies in testing requirements remain. Many thousands of potentially neurotoxic compounds whose introduction to commerce antedated passage of the Act remain untested, and there are no requirements at present for testing such compounds; these compounds, BHMH

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among them, were simply registered with the U.S. Environmental Protection Agency (EPA) and were added by EPA to the TSCA Inventory. Also, testing procedures for new industrial compounds have not been standardized; responsibility for deciding whether or not to test a new chemical and for development of testing protocols is left almost entirely to the discretion of chemical manufacturers. Governmental review of the toxic potential of new chemicals consists typically of examination of their structural formulae.

Although testing of BHMH for acute toxicity demonstrated ataxia, tremors, and possible convulsions in exposed rats, the manufacturer apparently did not consider the compound to be neurotoxic on the basis of these results and did not warn users of potential neurotoxicity. Also, no chronic testing of the compound was performed. The severe neurologic damage incurred by the workers who were exposed to BHMH provides an object lesson of the inadequacies of our present premarket testing procedures."

How do we determine whether a chemical substance has the likelihood of having an adverse effect on the human nervous system, and what new methods might become available that would serve to reduce the cost and the number of animals used in these types of experimental evaluation?

The present procedures of neurotoxicity evaluation essentially rely on the use of selected laboratory animals. The chicken has proven especially suitable to assess one class of neurotoxic agents, but the rodent and dog are most commonly employed to study compounds with unknown effects. Primates are rarely used, although they represent invaluable experimental subjects to model some types of human neurotoxicity that are difficult to recognize in a lower species. Two or three species of small laboratory animal may be required to detect neurotoxicity since one or more may be relatively refractory to the chemical substance under study. In an attempt to surmount this problem, toxicologists employ a range of doses of the test chemical, some of which may exceed the expected level of human exposure while others approach an environmentally significant dose. The numbers of

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animals required for neurotoxicity testing are much smaller than those needed to evaluate a chemical for carcinogenicity. Young adult animals are normally used, unless questions pertaining to fetal toxicity or neuroteratogenesis are being addressed when pregant dams form the subjects of study. Newborn animals have been used to investigate the neurotoxic properties of certain food additives and to model the action of chemical substances (hexachlorophene, lead, methyl mercury) on the developing brain. Test compounds are administered in known purity, varied doses, and for varying periods of time: i.e. a few days (acute study), 90 days (sub-chronic study) or throughout life (chronic study). Acute toxicity studies are highly relevant for predicting the effects of sudden human poisoning and of massive overexposure in an industrial setting. Subchronic animal studies have been employed to identify a number of neurotoxic substances, although negative results should be interpreted with caution since the additive effects of repeated exposure to low levels of neurotoxic agents may only be expressed after treatment periods longer than 90 days. Lifetime exposure is rarely used to evaluate industrial or environmental chemicals for neurotoxicity. Such studies are routinely carried out in cancer bioassays but, regrettably, sample animals used in these extraordinarily expensive experiments have not been available to determine whether the nervous system is also a target of chemical attack.

There are many methods to evaluate alterations in the nervous system of animals exposed to chemical substances with neurotoxic potential. Sometimes the changes are obvious to the naked eye, appearing in the form of convulsions, tremor, urinary incontinence, or paralysis. On other occasions, the response is more subtle and may require a battery of functional tests or neurological examination to detect a change in neurobehavioral status. Once a functional abnormality has been found, it requires further investigation by electrophysiological and/or morphological techniques to identify the site and nature of the chemical-induced change. A contemporary pathological examination is critically important to demonstrate the type of lesion and to assess whether it is likely to reverse if the test chemical is withdrawn. Few chemicals with human neurotoxic potential would be missed in sub-chronic studies of a range of doses in two animal species examined by simple neurobehavioral and morphological methods. The protocols for these methods will shortly be made available by the World Health Organization.

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While there is a clear need to subject existing and new chemicals to neurotoxicity testing, the backlog and future inventory of chemical substances would rapidly swamp the nation's capacity both in terms of available laboratories and personnel. We must provide more support for those academic and other centers that are struggling to develop or maintain a program of investigation into chemical neurotoxicity. Additionally, we must train more scientists in neurotoxicology as a subject that combines a solid understanding of the principles of neurobiology and toxicology. Finally, we must sensitize medical students and physicians to the increasing frequency of neurotoxic disease, and encourage them to search the patient's history for possible cause-and-effect associations between chemical exposure and nervous-system dysfunction.

Another important area for future endeavor is the development of more rapid methods to detect chemicals with neurotoxic properties. While the experimental animal will remain a cornerstone in the assessment of chemical neurotoxicity, other less expensive methods might serve to flag substances for further investigation. One technique is to compare the chemical structure of the agent in question with that of a known neurotoxic chemical. This deceptively simple method presently is only useful for certain classes of substances because of our limited knowledge of structure-toxicity relationships and the ability of some chemicals to change their form in the body from a relatively innocuous material to a potent neurotoxin. An example of this phenomenon is the solvent n-hexane which owes its chronic neurotoxic properties to another compound (2,5-hexanedione) that is formed from n-hexane in the body. Much more work on mechanisms of chemical neurotoxocity will be required before structure-toxicity considerations prove generally useful as a screen for neurotoxicity. Other test methods now under development include the use of non-mammalian species and tissue-culture models of the nervous system. Both will likely prove useful for the initial detection of chemical neurotoxicity and to determine mechanisms of neurotoxic action. Once these are understood at the biochemical level, it might be possible to devise rapid test-tube assays to screen chemical agents for neurotoxic potential. Tests of this type are already available for one class of neurotoxic agents (organophosphorus compounds).

While increased neurotoxicology research and testing will lead to reduction and improve control of environmental and occupational neurotoxic substances, there are other, hidden

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benefits in promoting this area of scientific endeavor. Neurological scientists are realizing that chemical substances with neurotoxic potential are useful probes to explore the normal nervous system and to model in animals some of those neurological diseases which afflict mankind. Two examples illustrate the point: MPTP, a contaminant of a synthetic heroin that induced a parkinsonian-like disorder in Californian drug addicts, has caused a revolution in our understanding of the possible causes of Parkinson's disease by allowing neuroscientists to reproduce a similar disease in laboratory animals. Similarly, BOAA, a natural neurotoxin present in a foodstuff that has crippled hundreds of thousands of people in Bangladesh, Ethiopia and India, holds promise as a tool to investigate Lou Gehrig's disease.

In conclusion: there is a clear need to test existing and new chemicals for neurotoxic potential. Methods for neurotoxicity assessment are well established but expensive. Cheaper methods will only be developed if we increase our understanding of the biological mechanisms underlying the many types of chemical neurotoxicity. Research and training budgets for neuroscience-based neurotoxicology must be increased if this goal is to be realised. A spin-off from this effort will be an increased understanding of major neurological diseases whose cause and prevention may thereby be established.

Reference

1. Horan, J. et al. Neurologic dysfunction from exposure to 2-t-butylazo-2-hydroxy-5-methylhexane (BHMH): A new occupational neuropathy. Am. J. Public Hlth. 75: 513-517, 1985.

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Mr. VOLKMER. Thank you very much for your testimony, Dr. Spencer.

I have several questions here. I think I'd like to begin with Mr. Clay.

In the first place, in your statement I'd like to know what you mean by "important emphasis."

Mr. CLAY. I think we mean by that—I know we mean by that—that it's coming along. Before 1981-82, that we didn't have any guidelines, which was a common excuse for not doing it. By important emphasis, I think it's one that's coming.

If you look at our more recent actions, you'll find a much greater percentage of requiring testing for neurotoxicity. So it's a growth area for us.

Mr. VOLKMER. Now we've had TSCA since 1976.

Mr. CLAY. Yes, sir.

Mr. VOLKMER. This is 1985. That's 9 years. That's simple.

Mr. CLAY. Yes, it certainly is. Engineers can handle that so far.

Mr. VOLKMER. Right. And we're just now growing into testing for neurotoxicity?

Mr. CLAY. Yes.

Mr. VOLKMER. Is that right?

Mr. CLAY. That's correct, sir.

Mr. VOLKMER. And it will take us another how many years to where we have a Government structure in place to test all new chemicals for neurotoxicity?

Mr. CLAY. Well, I don't think that, certainly as TSCA is written now, that we'll ever be in a position to do that, nor I'm not sure that Congress intended for us to test all new chemicals if they come on.

Congress designed TSCA to be a prenotification for premanufacturing. It's a notification scheme. It's not a registration scheme such as pesticides or drugs, for example, which are registration schemes.

All the company is required to do under TSCA is notify us 90 days before they start manufacturing to—and then the burden is on the Government to see if we have a problem. So it's an entirely different concept.

We get now about 1,500 notifications a year of chemicals coming in as new chemicals, and about half of those are polymers, which I think most people would agree are not likely to be of neurotoxical concern.

Of the ones that we get, about 110 out of, say, 1,500, we'll take some sort of control action, in some cases based on neurotoxicity; more often on some other effect.

So——

Mr. VOLKMER. You do have guidelines for testing for neurotoxicity. Do you have guidelines to determine what chemicals coming on line should be subject to testing?

Mr. CLAY. No, we do not have a—the American system is not designed to require testing—the burden of the Government is on a chemical-by-chemical basis to say testing is needed on a particular chemical; the European system, by contrast, requires testing, but theirs is a premarketing system as opposed to premanufacturing system.

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So the U.S. system does not require testing prior to doing it. All it requires is notification, and then the burden is on EPA to decide if we think there is a problem, so that we can require testing on a chemical-by-chemical basis.

Mr. VOLKMER. What—well, what do you use as a criteria to determine, then, which chemicals should be tested for neurotoxic effects?

Mr. CLAY. In some cases we, in fact, get some data with us, but, as most people will point out, we get very little data. Often we rely on professional judgment in terms of the staff that we have at EPA and rely on the structure activity relationships, that was mentioned by some of the other panelists, to see if we believe there would be a neurotoxic problem or other sort of problem.

Mr. VOLKMER. How many neurotoxicologists do you have on staff?

Mr. CLAY. Two.

Mr. VOLKMER. To review how many filings by manufacturers?

Mr. CLAY. Well, they don't review each and every one. We get about 1,500 a year, sir.

Mr. VOLKMER. Yes, but, of those, surely there's so many of them that somebody's going to have to look and determine—they're not all polymers, so somebody's going to have to determine out of certain many—what, 100, 200, 300, 500 a year——

Mr. CLAY. Well, about 100 and——

Mr. VOLKMER [continuing]. To look at just, first, some—somebody surely is looking at these things.

Mr. CLAY. We are looking at them. We have a stage process, a very detailed process, which I will be happy to provide for the record, if you'd like, sir, in terms of how we look at new chemicals.

But we essentially have teams of people looking at them where the neurotoxicity—neurotoxicologists participate on those teams, but often—often it would be the case that the exposure situation will be such that there's no cause for concern.

We have to keep in mind that the risk of a chemical is a function both of its hazard, inherent hazards, including neurotoxicity, as well as the amount of exposure. In some cases these are extremely small chemicals, I mean sometimes on the order of grams or what have you.

So we have to look at the whole risk picture, and we have a process by which we continually look at chemicals and the more risky ones are passed along for more detailed review. And, as I said earlier, I think about 10 or 12 percent, 16 percent, in that order of magnitude, go into more detailed review.

Mr. VOLKMER. Now let's assume that in this staff review we have chemical X that is suspected of possibly toxic—of neurotoxic effects. What is the procedure then?

Mr. CLAY. Well, one of the things that we'll—we will look at will be—it's suspected of being a neurotoxic problem. We'll look at the anticipated exposure in terms of what's happening. We'll look and see what the company says they're going to use it, how it's going to be manufactured.

Mr. VOLKMER. Let's say there is going to be, to use your word or a word that has been used here, significant exposure to a number—several thousand people in the manufacturing and use of it——

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Mr. CLAY. That would be highly——

Mr. VOLKMER [continuing]. On an annual basis.

Mr. CLAY [continuing]. Highly unusual for a new chemical. Most of them are very small volume.

Keep in mind that the total volume of all the new chemicals we've seen are approximately—and started to manufacture are approximately equal to, say, the exposure to formaldehyde in terms of poundage or something like that.

New chemicals are typically very small and, more likely, we'll see 2 or 3 workers exposed or 10 workers exposed, or something like that. Seeing several thousand exposed would be highly unusual. I'm not sure we've ever seen that many.

Mr. VOLKMER. Let's say you even have two or three. Those are human beings. Now are we going to say, because there's only two or three people exposed, that we don't worry about it?

Mr. CLAY. No. We're going to take a look, and we're going to have the engineers and the exposure assessment people we have on the team look and see if, in fact, we believe there will be exposure to that chemical. Oftentimes the chemicals are used as intermediates and never isolated. They don't come in contact with humans, and there's no problem that way.

If, in the end, though, we believe there is a problem, then the company has said that they are going to require the use of respirators or gloves, we will enter into a consent order under section 5(e) of TSCA requiring them to do so. So if we believe there is a problem, an acute problem or a chronic problem, or where we suspect such, we will use the authority of TSCA to require them to take the appropriate safety regulations, and that's worded in such a way—that's pending the development of testing. They can either do the testing that we demand they do or they can control such exposure at a level we don't believe there will be a risk.

Mr. VOLKMER. In other words, if they agree to use some type of respirators and put those on warning labels, that will be sufficient?

Mr. CLAY. Yes, sir; we believe that will reduce the risk, primarily through controlling exposure, not the toxicity.

Mr. VOLKMER. Even though the respirator may really not take care of the inhalation of the chemical——

Mr. CLAY. Well, we believe the——

Mr. VOLKMER [continuing]. Sufficient?

Mr. CLAY. We believe we have experts in respirators, and we believe the type we specify—we don't just say "respirator;" we do specify the type of respirator, and we believe that what we have is, in fact, appropriate when we say "respirator."

Mr. VOLKMER. Even without testing the chemical?

Mr. CLAY. Well, what we're saying is—again, let me go back to the—a risk is a function of the inherent toxicity of the chemical and the exposure of the chemical. If there is no exposure of the chemical, no matter how toxic the chemical is, there will not be a risk, in which case we operate not under significant risk but under unreasonable risk basis, and we're always balancing the cost and everything.

Mr. VOLKMER. All right. Now, again, are we talking about the inline type of respirators with the clothing that will take care of it or are we just talking about sometimes the respirator that looks

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like a gas mask or something like that that goes over, that actually is used to filter the air that a person is breathing?

Mr. CLAY. We specify a range of respirators, and I can provide for the record the types that we recommend, if you like, sir.

Mr. VOLKMER. I would like to have that.

[Material to be supplied follows:]

Section 5(e) orders normally specify one of three respirator types: Positive pressure, air supplied; air purifying with high efficiency particulate filter; above with paint mist pre-filter. Either full face or half-face masks may be used.

Mr. VOLKMER. Now I'd like to go, then, to—Dr. Spencer, you've cited the use of the BHMH, and that was in the Texas, I believe, incident.

Dr. SPENCER. Yes, sir.

Mr. VOLKMER. When did that occur?

Dr. SPENCER. That occurred in September 1979.

Mr. VOLKMER. TSCA was here in 1976?

Dr. SPENCER. Yes, sir; effective 19—January 1, 1977.

Mr. VOLKMER. Now what did you do on BHMH?

Mr. CLAY. I don't know.

Mr. VOLKMER. The manufacturer made a filing, undoubtedly.

Mr. CLAY. Let me consult for a second.

[Mr. Clay consults his staff.]

Mr. CLAY. That particular chemical, what the Congress said when they passed, it says we should establish an inventory of existing chemicals that were in commerce at the time prior to passage of TSCA. That we did, and we added some 55,000 chemicals to the inventory. That was one of them, so it was one of the ones grandfathered in as an existing chemical and would not have to come in for a new chemical.

Mr. VOLKMER. Dr. Spencer.

Dr. SPENCER. I believe it's also true to add that the structure of this compound was studied by EPA officials, and it was judged to be no threat.

Now one is very sympathetic with the plight that staff at EPA may be under. However, I would suggest that we are fooling ourselves if in 1985 we believe that we have a sufficient understanding of chemical structure and interaction with the brain to be able to predict which compounds are likely to cause either beneficial or adverse effects, excepted—a few classes of compounds excepted from that statement.

In actual fact, had I or anyone else looked at this particular compound, BHMH, we would have probably drawn the conclusion that it would have been safe, which is presumably the conclusion that EPA drew, and I would have been in the same boat if I had been foolish enough to attempt such a hazardous venture.

We would have said it was probably safe because, looking at the structure, we would have seen that it was unable to break down in the body to a particular compound that we know causes neurotoxicity in association with chemicals of somewhat related structure.

What I'm trying to get across is that there is absolutely no way in 1985—perhaps in the 21st, 22d century, sure, but absolutely no way in 1985 can we predict with any degree of confidence structure toxicity relationships for the vast majority of neurotoxins and also

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for other target organ toxins, and we will not be able to until we understand mechanisms.

Mr. VOLKMER. Is that because we haven't had sufficient research into the structural effects?

Dr. SPENCER. That's absolutely right.

Mr. VOLKMER. And what is the progress of research on it at the present time and the prognosis for the future?

Dr. SPENCER. The wheels are grinding into action. At the Albert Einstein College of Medicine we were fortunate enough to be, I guess, world leaders in developing neuroscience-based neurotoxicology. Dr. Weiss, as you heard from this morning—again, world leaders in the area of behavioral science and the action of toxic chemicals on behavior.

Other centers are picking up the obvious slack, and we're seeing some of the major medical schools develop programs in behavioral and neurotoxicity.

The signs are good, but, as we mentioned this morning, in the academic centers graduate students and postdoctoral fellows are totally and utterly frustrated and junior faculty totally frustrated by the almost impossibility of obtaining any grant support in this area, and are leaving for other pastures.

And so the will and the interest is there, but, unfortunately, as we mentioned, our universities are embattled at this point.

Mr. VOLKMER. Before I go on to something else, Dr. McMillan, would you like to comment on any of that final statement Dr. Spencer and Mr. Clay——

Dr. MCMILLAN. There is a tremendous amount of competition for the interest of those few students that are being trained in toxicology. Although many universities have geared up and have developed graduate programs in toxicology to turn out Ph.D.'s, the number is still simply a trickle compared to what is needed.

Neurobehavioral toxicology is simply one of many areas of toxicology that must compete for that student pool. With the lack of research money that's available for doing research in neurobehavioral toxicology, the tremendous competition from other fields in the biomedical sciences, we just aren't getting very many.

If I may use my own institution as an example, we currently have 24 or 25 students at various stages of training for Ph.D.'s in toxicology. At the moment one of those students has expressed an interest in neuro behavioral toxicology. So we are not competing very well even within the field of toxicology for those bright students.

Mr. VOLKMER. Thank you very much.

Mr. Clay, before I forget, you may have already agreed to do this, but I just want to make sure—that you have furnished us for the record, if you have such a memorandum or anything, the criteria that you use in determining, in other words, how many people are exposed, the toxicity level, et cetera, for determining which chemicals would be undergoing tests or be required to have a warning label or that type of thing.

Mr. CLAY. You mean more description of the process? We'll provide you what we have.

Mr. VOLKMER. Fine. Yes, if you have a description of that process, I'd like to have that for the record.

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Mr. CLAY. Certainly.
[Material to be supplied follows:]

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I. REVIEW OF NEW CHEMICAL SUBSTANCES UNDER §5 OF THE TOXIC SUBSTANCES CONTROL ACT (TSCA)

- Section 5 of TSCA mandates the Environmental Protection Agency (EPA) to review the potential effects of new chemicals prior to manufacture or import.
- In order to meet the statutory mandate of TSCA §5, the Agency developed the PMN Review Program.
- The purpose of the PMN program is to determine, before a new chemical is manufactured for a commercial purpose, whether data submitted with the PMN, or otherwise made available to the Agency, indicate that proposed uses of the substance may result in an unreasonable risk of injury to health or the environment.

A. Background

- Premanufacture notification program began in 1979.
- Notification to the Agency (EPA) is required of any person who intends to manufacture or import a new chemical substance.
- Notification is required at least 90 days before beginning manufacture or import.
- New chemical substance is defined as any chemical substance not on the TSCA Chemical Substances Inventory (published in 1979) by EPA and covers chemicals in commercial production between the years of 1975 and 1979.
- New chemical notice requirements as defined under TSCA apply only to general consumer and industrial chemicals. They do not apply to pesticides, drugs, food additives, cosmetics, or tobacco products.
- Over 6,000 notices have been received since 1979*. In FY-84, we received almost 1200 notices and we received 1464 by the end of FY-85. This breaks down to one PMN received every 90 minutes.

B. Data Requirements

- Submitter must complete premanufacture notification (PMN) form which includes substance identity, uses, production volume and exposure data.

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- Although toxicological data need not be developed solely for premanufacture notice, it must be submitted to the extent that they are known or reasonably ascertainable by submitter.

- However, EPA has broad authority to obtain such data when it is needed for evaluation of potential risk.

II. NATURE OF EPA'S PMN REVIEW

- Stringent review of potential risks posed by manufacture, processing, use and disposal and any resulting action must be done in 90 days.

- For good cause, EPA may extend the review period for an additional 90 days. This is most often done to allow EPA to take regulatory action. Companies are encouraged to voluntarily suspend the review time if they are preparing additional information.

- Each notice proceeds through a screening process to determine whether more detailed review is required and to identify candidates for regulatory action.

- Focus is on relatively few new chemicals of greatest concern - those which are structurally related to known toxic chemicals, and those about which little is known.

- Detailed assessment consists of:

  - analysis of chemistry,

  - selection of structurally analogous substances,

  - literature searches for toxicity data,

  - analysis of available test data on a substance or analogous substances,

  - analysis of potential releases to the environment,

  - exposures to workers and general population,

  - calculations of potential concentrations in surface waters,

  - additional uses which could significantly alter exposure.

- Before taking regulatory action EPA always considers economic benefits of the new substance and cost of recommended action.

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III. REGULATORY OPTIONS

- EPA has authority under §5 to ban or regulate new chemicals if available data indicate that the chemical will present an unreasonable risk, or if
- Available data are insufficient for a reasoned evaluation of risks and EPA believes it may present an unreasonable risk or that there may be substantial production and exposure. In this case, regulation remains in effect until sufficient data are provided.
- The number of chemicals that fall under Agency Regulation is quite small. For FY-84 only 45 PMN's (4%) required regulatory action. In FY-85 only 47* (3%) fell into this category.
- Informal regulatory actions can also occur in the form of voluntary testing or controls, or actual withdrawal of PMNs by companies in the face of §5 action.
- When risk warrants, controls may be required while testing is being conducted, or EPA may simply prohibit any commercial manufacture until testing is completed.
- In some cases, EPA may not require testing immediately. Rather we may allow limited manufacture or use of the substance pending the development of data, frequently under the terms of a consent order, a negotiated process whereby a company agrees to have certain restrictions placed on the new chemical. This allows innovation to continue and society to receive the benefits while protecting against unreasonable risk.
- For example, this approach may be taken if:
  - significant exposure can be prevented by protective equipment and/or engineering controls;
  - such exposures are controlled by the PMN submitter;
  - there is no consumer exposure; and
  - testing costs are very high considering production volume, profitability and other factors;
- In some of these cases, EPA may require testing to be submitted at a future date, when a certain production volume is reached ("triggered testing").

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- o If we cannot take a consent order approach because of the above factors, we may ban the new substance.

IV. FACTORS OF EVALUATION FOR REQUIRING TEST DATA

- o Evaluation of the adequacy of data in PMNs and of the potential risks posed by new chemicals depends on a broad range of factors--including chemical structure, use, exposure, cost of testing, and similar questions.
- o Factors must be viewed in combination.
- o When the requirement of health effects tests may be invoked:
  - if exposure associated with expected uses and production volume is significant, greater certainty is needed that serious effects will not occur;
  - data on structurally related chemicals or data on the PMN substance indicates substance may have toxic effects, but more data are required;
  - specific tests can be performed which will significantly reduce level of uncertainty;
  - the cost and time required for testing is not unreasonable, given the market potential of the chemical and the seriousness of the effects;
- o Requirement for ecological toxicity testing may be invoked when:
  - evaluation of manufacturing, processing, or use indicate potential for significant environmental release;
  - evaluation of physical/chemical properties (e.g. solubility in water, potential to bioaccumulate, etc.) indicates exposure to biological organisms given potential for release;
  - evaluation of substance and structurally related chemicals indicates potential toxicity.
  - available data do not provide an affirmative basis for concern but uncertainty exists and levels of exposure warrant the development of additional data.

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V. "TRIGGERED" v. UPFRONT TESTING

- Many new chemicals cannot support cost of testing before production begins. TSCA requires that we do not unduly impede innovation.
- Many chemicals could support the cost of testing after they have been in production for some time.
- As the volume and length of time of production increase, exposure also increases - further justifying the need for testing.
- In many cases, we can impose exposure controls until it is reasonable to ask for data.
- The following factors are considered when deciding whether to trigger testing, to require testing "upfront", or to impose controls without a testing requirement:
  - acute vs. chronic effects.
  - short-term vs. long-term testing.
  - seriousness and likelihood of effects.
  - extent and significance of exposure.
  - whether exposures can be controlled adequately via §5(e).
  - impact of testing cost on "marketability" of the chemical.
  - societal benefits of the new chemical.
  - projected production volume.
  - availability of substitutes.
  - "case history" of similar PMNs.
- To decide at what volume the testing should be required:
  - the starting point is the production volume at which the profits from the chemical will support the testing cost.
  - the factors listed above may be applied again to adjust the volume up or down.
  - similar PMN decisions are reviewed, where appropriate, to assure consistency.

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- To date*, 13 Consent Orders (16 PMNs) have involved triggered testing.

VI. DESCRIPTION OF WHAT §5(e) CONSENT ORDERS (COs) COVER:

1. Contract Manufacturer-

- An EPA consent order with a company requires the company to enter into a separate agreement with a "Contract Manufacturer" to manufacture, process or import the PMN substance.

2. Protective Equipment-

- Most COs require the use of some type of protective equipment including impervious gloves, boots, and/or suits, safety goggles, face shields or respiratory equipment. In addition, such a requirement may involve fit tests for the respirators and impermeability tests for the gloves.

3. Warning Labels/Statement-

- Labels carrying specific warning language are often required to be placed on containers of the PMN substance. Warning statements made by management to workers are also required. The warning must specify not only the method of protection the handler should use, but also the type of risk involved with the substance's use.

4. MSDS/Notification Letters-

- As a condition of distribution of the PMN substance, the company may be required to notify the health and safety representative of the receiver of the requirements of the order by means of a Material Safety Data Sheet and a notification letter.

5. Reporting Requirements-

- The Company is required to report to EPA within 10 days of its receipt any information which indicates that any person to whom it has distributed the PMN substance has failed to comply with any conditions specified in the CO.

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6. **Limitations of Packing, Production, Use, Distribution and Waste Disposal-**

   - Limitations on any or all of these activities are incorporated in the consent order on a case specific basis.

7. **Worker Training Programs-**

   - The company is required to inform its workers of the health concerns of the substance, and the protective equipment necessary to protect the workers. Old orders require the company to inform the workers either in writing, or as part of a training program. Newer orders require that both methods be used.

8. **Environmental Controls-**

   - These include a requirement that wastes be discharged to a specific facility and/or that packaging of the substance be leak-proof.

9. **Testing Trigger-**

   - As a specified production volume is reached, the company must cease production of the PMN substance, unless it submits results of a specified test sufficient to permit a reasoned evaluation of the effects of exposure.

10. **Monitoring-**

    - During manufacturing and/or processing, workplace air concentrations must be monitored. If not kept below a specified level, respirators are required to be worn.

11. **Record Maintenance-**

    - Specified records are required to be kept by the company until 5 years after the date they are created, and must be made available for inspection and copying by EPA.

VII. REGULATORY EXPERIENCES TO DATE*

- In lieu of regulation, submitters sometimes elect to test voluntarily (our figures show only approximately 2% offer to do so).

- A ban has been required for less than 1% (15 PMNs) of all PMNs submitted.

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- o EPA has issued consent §5(e) orders on 103 chemicals, 16 of which involved "triggered testing."
- o 4 PMNs have been subject to §5(f) rules.
- o In addition to those §5 actions which EPA issued, 94 PMNs were withdrawn by submitters in anticipation of EPA action.
- o If regulation under projected use and associated exposure is not warranted, but different use with different exposure could lead to concern, EPA may issue a Significant New Use Rule (SNUR) which would require notification should use or exposure change.

VIII. EXEMPTIONS (TME'S, POLYMER, & LOW VOLUME)

A. Test Marketing Applications

- o In the past, we have allowed companies to manufacture some chemicals on a "test-market" basis if they meet certain criteria.
- o Test-market reviews are conducted within 45 days. Companies must prove manufacture will involve less than full-scaled production, and have established a pre-determined volume, and a defined number of customers.
- o If EPA finds no unreasonable risk to health or environment, the test-market exemption will be granted.
- o To date, 378 TMEAs have been received.

B. Polymer and Low-Volume Exemptions

- o Just this year, however, we have added 2 new categories of exemptions: Polymer and Low-Volume Exemptions.
- o These two new categories receive abbreviated 21-day review, and allow industry to begin manufacture earlier than if they had submitted under PMN review, but again, must meet a strict list of criteria to be declared eligible.

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- In the case of a **Polymer** Exemption, the substance must have a number-average molecular weight of 1,000 or greater or, must be a polyester made from a specified list of low concern reactants. Certain types of polymers are excluded, however, to ensure the exemption is limited to low concern polymers. Since January of FY-85, 200* Polymer Exemptions have been received.

- The **Low-Volume** Exemption for chemicals manufactured at 1,000 kg/yr or less, includes specific information requirements in the notice, requirement of another notice by the manufacturer before a change in site of manufacture or use takes place, and that only one manufacturer may make a given chemical under this exemption. Subsequent manufacturers must file a full PMN. 168* Low Volume Exemptions have been received in the program since their initiation in June 1985.

- Under the low-volume exemption, chemicals with the potential for serious human effects or significant environmental effects under conditions of exposure are excluded from eligibility.

- EPA can deny any exemption during its review if it determines that the substance fails to meet the terms of the exemption, or if there are significant unresolved issues concerning risk.

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Mr. VOLKMER. And, as I understand it, under the present law, then, you are not permitted really to require premanufacturing or premarketing tests by manufacturers; is that correct?

Mr. CLAY. Not based solely on the fact that they are a new chemical. We have to make a finding of—it may present unreasonable risk of injury to health or the environment or be produced in sufficiently large volumes. So we can do it. We must do it chemical by chemical, and we must do it by order, and we must make those particular unreasonable risk findings. We can't, just because a chemical is new, require testing.

Mr. VOLKMER. So you'd have to do it to show some data, and the manufacturer, if he submits to you no data base, you would have to prepare your own data?

Mr. CLAY. Well, we don't require—we don't do our testing ourself. We do it based on the structure—the findings is "may present" while regulating an existing chemical is "will present," and "may present" is an easier finding for us, but, nevertheless, we must have something to base it on, either a structural analog or whatever data—the manufacturer is required to give us any data that he may have produced, but oftentimes they don't or they'll just——

Mr. VOLKMER. If they just fail to do toxicity tests, they can't submit any data, then, can they—do they?

Mr. CLAY. They're not required to; no, sir.

Mr. VOLKMER. Right.

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Mr. CLAY. Unless we make a finding of a "may present," which we do in some percentage of the cases.

Mr. VOLKMER. How often have you done that in, let's say, the last 5 years?

Mr. CLAY. I don't have it for the last 5 years.

Mr. VOLKMER. In the last year, 2 years, whatever——

Mr. CLAY. No. What I have is last year, sir. We have—we had a total of 1457 PMN's received. We took control actions on 110 of those. That includes the types of orders we talked about. It also includes voluntary testing. Oftentime a company will suspend the clock—keep in mind we have 90 days to do this—and do voluntary testing, or they'll take other voluntary actions or in about half the cases they'll just withdraw the PMN, because these are new chemicals, most of—not most of which, about half of which will never come to market anyway, and if they're going in difficulty with us, they'd just as soon withdraw as to do any testing.

Mr. VOLKMER. How many of those 110 did you get consent agreements, provide warning labels, or respirator-type equipment, et cetera?

Mr. CLAY. There were 35 consent orders. I'll have to check to find out what percentage required respirators. It's very typical to have the consent order to say that you must wear a respirator, gloves, what have you, pending the development of data, and since the data costs more than using the control equipment, they'll generally keep using the control equipment.

I might also add that we do sponsor research in terms of gloves and respirators at some of our in-house EPA laboratories, ourselves jointly with their pesticide programs trying to look, because a glove is not a glove, either. And the dermal exposure is often becoming an important source as well as just inhalation.

Mr. VOLKMER. Yes.

Is there any possibility that you could require industry to conduct inexpensive screening instead of relying just on a structural analysis?

Mr. CLAY. Well, that's something that the—that has been debated and it's been introduced in—TSCA is not reauthorized at the present time, and the Senate version that was introduced last year but did not go anywhere did require a base set of testing. That will generally—that will have to be done by statute.

I have to take—the way the law is written now, I have to take chemical-by-chemical and make a finding of a "may present an unreasonable risk."

There are some large economic consequences, too——

Mr. VOLKMER. If we did—I'd like to pursue that just a moment. If we did require that type, how much more manpower would you have to have to handle the data that would be generated by it?

Mr. CLAY. I'd have to provide that for the record. It depends on what types of data that you have. In some cases it may be easier because I'll have the data rather than having the people making a different—making professional judgments.

Mr. VOLKMER. Right. And rather than doing the——

Mr. CLAY. On the other hand, it would probably greatly reduce the amount of workload because most new chemicals then would not be produced, because they can't afford the data. The profit

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margin on chemicals are—is generally very low, and we estimate that when you take about 25 percent of the profit margin for testing, they'll generally withdraw rather than doing it, because keep in mind we're early on in the process but before manufacture, and the way the system works, they must notify us. If we say nothing, they're free to go ahead. When they start manufacturing, they must notify us. And when they start commercial selling—and we get notified about half the time. So about half the ones that come through and we look at never go into commercial production for a variety of reasons.

Mr. VOLKMER. Well, how much would a battery test for, say a screening battery test, cost a manufacturer?

Mr. CLAY. Well, the system used in Europe called the—in the European Community is called the base set. That costs on the order of $40,000 to $50,000. That does not include neurotoxicity testing, by the way. They have a tiered system of testing requirements where the base set—and then they have several upper tiers, none of which require neurotoxicity testing. That one costs $50,000. You can clearly start out with something less than that.

Keep—also we've got to keep in mind that, while we are accused of having a preoccupation with cancer or looking at structural that way, oftentimes we'll be regulating on another end point, often cancer or suspected cancer, which will result in exposures which are less than such that we protect for the neurotoxicity effects also. That's certainly true in the existing chemicals, and it's true somewhat in the new chemicals.

Mr. VOLKMER. You see—in other words, it can be done to test for both carcinogenicity and neurotoxins, then?

Mr. CLAY. I'm saying that, if we're controlling the chemical based on carcinogenesis, we would more than likely take care of—we'd have the levels down to such that any neurotoxicity concern would also be taken care of.

Mr. PACKARD. Would the chairman yield on that question?

Mr. VOLKMER. Yes, I yield on that.

Mr. PACKARD. Is there a significant savings by combining testing procedures rather than doing them for individual concerns or purposes?

Mr. CLAY. Well, the eight testing guidelines that we have, and when we are going to require them, often piggyback on—can be added on to other tests. So there's an incremental cost. So there certainly is a cost if they're going to do it in terms of, if you're doing some other tests, you can often add some of the neurotoxicity onto it.

My understanding—and I'm not a scientist—sometimes the original toxicologists do not like that because you're messing with their animals, and there seems to be some compounding factors, so it's not as simple as it might seem to the outside person.

But our tests are normally an increment onto some other test that's already being done, rather than free-standing test.

Mr. VOLKMER. I just want to make sure that I understand, so we have something clear for the record in this last statement that you made in regard to carcinogenicity and testing for that.

Are you telling me that if you find that it's not cancer-causing that it's not neurotoxic?

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Mr. CLAY. No. No, sir; that's not what I meant at all. Let me clarify it.

Mr. VOLKMER. I'm trying to find out——

Mr. CLAY. What I said, if I knew—and this is particularly true for an existing chemical where I'll have a long-term bioassay, and if I know that it is an animal carcinogen, as I'm trying to regulate it or set a level, the level I will set to make sure that the carcinogen can be used in a safe manner would take care of any neurotoxic effects, because that would generally be at a lower level. I allow a much lower exposure based on the carcinogenesis as opposed to the neurotoxicity.

Mr. VOLKMER. What you are telling me, then, is, unless I just don't understand what you're saying, is that if you reduce the level of exposure, the risk, for cancer at a low enough level, then there's not going to be a neurotoxic effect?

Mr. CLAY. That is, I believe, generally true.

Mr. VOLKMER. Do you agree with that, Dr. McMillan?

Dr. MCMILLAN. Maybe I'm misunderstanding what Mr. Clay is saying.

Mr. VOLKMER. I think I'm misunderstanding, or I hope I am.

Dr. MCMILLAN. I don't think that eliminating the cancer risk also eliminates the neurobehavioral toxicity risk at all. If he's making the point that if you show that a chemical is carcinogenic that that is probably going to eliminate the behavioral problem as well, because of the levels that will be required for the carcinogenic testing, I think that will be true for some but probably not for all chemicals.

I don't—I suppose it doesn't really matter what you eliminate the chemical for, whether it's carcinogenesis or neurotoxicology or something else, if it's eliminated. But I don't think that eliminating the problem in one area necessarily has to do—has anything to do with eliminating the problem in another area.

Mr. VOLKMER. Do you have any comment, further comment, Mr. Clay? And then I want to ask Dr. Spencer to comment.

Mr. CLAY. I think that's perhaps a better explanation. Keep in mind I go back to my risk as a function of both the inherent hazard and the exposure. And if my concern of the hazard is carcinogenesis, I generally believe that if I'm controlling for that, I'm controlling for most other end points also, because I keep the exposure so low that people are not exposed at levels required to do it.

Mr. VOLKMER. In other words, basically your premise is that, if the exposure level is so low as far as carcinogenicity, and you reduce that risk to such a low level of exposure, and the chemical itself, the structure of it, the combination, that the chance of cancer, say, is zero, then you don't have to worry about neurotoxicity? That's what I get from you.

Mr. CLAY. Well, we never reduce anything to zero. We're always doing risk balancing, so some small level. I'm not saying zero; I'm saying it's more than likely controlled, and I think in the majority of cases it would be controlled.

Mr. VOLKMER. Dr. McMillan, again?

Dr. MCMILLAN. It's an untested assumption.

Mr. VOLKMER. Dr. Spencer.

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Dr. SPENCER. Well, it's an untested assumption, I agree. What is intriguing is that it is perceived that the cancer risk is a greater risk than the neurotoxicity risk. Certainly the large majority of—certainly carcinogens have the potential to kill, but I'm not sure how one would rate that against the risk of a neurotoxin that has the potential to cripple. I don't know how to make that equation.

Mr. VOLKMER. Would you say disabled as well as crippled?

Dr. SPENCER. Yes; certainly.

Mr. VOLKMER. Now there is a question, Is death more severe than 30 years of disability?

Dr. SPENCER. Well, of course, we have great hopes for the treatment of carcinogenicity and a lot of progress has been made in that area. We can't do anything at all if we, for example, have a chemical exposure which precipitates brain degeneration. There's no way of reversing that at this point and not for the foreseeable future.

Mr. VOLKMER. Now how many of the 110 from last year did you require actually testing being done by the manufacturer? Did you find that there is a—what is the word——

Mr. CLAY. Unreasonable—may present an unreasonable risk of injury.

With the way the law is structured, I don't require them to test. I can say you can't make it until you test or I can say you've got to keep the level of exposure down through the use of respirators or gloves or what have you to some agreed-upon level or you must test. And many times the use of TSCA does not generate the data; it generates the control action because companies make an economic decision—it's easier to control as if it were a very dangerous chemical than to go out and find the testing to prove it is or is not.

Mr. VOLKMER. In other words, what I'm getting from you, probability is that not one manufacturer then decides to go through the testing procedure?

Mr. CLAY. Some are voluntarily testing, providing the data. So not one is not true, but I mean the vast majority would probably accept a control action in lieu of testing.

Mr. VOLKMER. They'll either do the control or not do the manufacturing?

Mr. CLAY. That's right, sir.

Mr. VOLKMER. All right. So we're really not doing any stringent testing for new and the inventory chemicals—is really what's happening; isn't that correct?

Mr. CLAY. Perhaps, sir, I wouldn't phrase it that way. I think for the new chemicals we have a reasonable program running. For the existing chemicals the law requires us to form an interagency testing committee to recommend chemicals to us for testing. They have done so. About 75 chemicals have been recommended for testing. About 30 of those we believe we could not make the findings required under section 4 because the chemical wasn't made or something like that, so it dropped. But the rest of them are being tested either by rule or voluntarily. So in the existing chemical we are doing it at a fairly substantial cost.

Mr. VOLKMER. Out of 50,000, we're doing 75 or——

Mr. CLAY. Less than that.

Mr. VOLKMER [continuing]. Less than 75?

Mr. CLAY. Less than 75.

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Mr. VOLKMER. Less than 75. We've ruled out the possibility that the other 49,000, whatever the figure is, are not neurotoxic, then?

Mr. CLAY. No, sir; we have not. I mean, as the National Academy of Sciences pointed out, we have very little information on those.

Mr. VOLKMER. Then the final question I would like to ask all the panel really is, Are we saying to the people who use these chemicals and to the workers who manufacture them that they're the test group?

Dr. Spencer.

Dr. SPENCER. If we, with due respect to Mr. Clay, if we are going to say that the EPA has a program in place that is reasonable, I think the word was, to detect and prevent exposure of the populous to chemical substances that potentially would cause nervous system—if we are going to make that assumption, then undoubtedly the working man, among others, is going to be the test subject, because I would like to say as strong as I can that if the basis for Mr. Clay's comments, and using the adjective "reasonable," is based on the present practice of reviewing structure and guessing toxicity or activity, then we are going to get—we are going to let many, many compounds through, because that science does not exist. It's a guessing game at this point; it is not a science.

Mr. VOLKMER. I'd like to have one final question here with regard to this and then we'll permit Mr. Packard.

As I understand, in 1981 EPA proposed a test rule for methylene chloride because the interagency testing committee said that methylene chloride was a neurotoxin. EPA's proosed test rule did not require any testing for neurotoxicity. In 1984 the EPA decided not to test methylenechloride at all. Now we learn that the Office of Toxic Substances has classified methylene chloride as a possible carcinogen and is going to start the rulemaking process to regulate it.

Why do you have to wait until you know or have, again the language within the law, that the substance can possibly cause cancer before you regulate it when you knew 5 years ago that it was a neurotoxin, and people have been exposed to it every day since then?

Mr. CLAY. Well, in 1981 we did know that it was—had acute neurotoxic effects.

Mr. VOLKMER. You did or did not?

Mr. CLAY. We did, sir.

Mr. VOLKMER. Did not?

Mr. CLAY. We did know it had acute effects.

Mr. VOLKMER. You did know?

Mr. CLAY. Yes. Because they have effects, though, again does not mean we're initiating regulatory action. We did not at the time propose for the chronic neurotoxicity effects because there were no standards. Our standards didn't come out until 1982-83.

In 1984, when we withdrew the—when we made the decision not to test, guidelines were available. However, we still believed that the chronic effects would be at no less than the acute effects, which we already knew we had some liver effects and we had a strong suggestion of carcinogenesis, and that we had the flawed NTP study at that time and NTP had already agreed to, in fact, to repeat the study.

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In May 1985, when we made the section 4(f) finding—section 4(f) was a mechanism Congress put into the act for us to put things at the top of the list to regulate. Section 4(f) itself is limited to not include neurotoxicity. Section 4(f), which is the primary congressionally-mandated part of TSCA, says that harm to humans from cancer, gene mutation, or birth defects. We made that finding, then, in May 1985, and sometime within the next few days we expect the Administrator will sign an order doing the advanced notice proposed rulemaking.

Keep in mind that we generally believe that if we do regulate based on carcinogenesis, we will in fact take care of the neurotoxicity problem also.

Mr. VOLKMER. And on the basis of that, if you regulate it, again, it will either no longer be used or manufactured because of carcinogenicity or, two, on the basis that you believe that you can show that the measurement as far as use, environment, et cetera, will be of such small risk that it will not cause—be carcinogenic. Is that correct?

Mr. CLAY. That is generally correct, sir. We keep in mind that the solvents are—society I don't think is going to have solvents going away. And one of the things we are doing is trying to look at solvents as a whole category of chemicals, because it doesn't do any good to take away methylene chloride if they all go to something else equally bad and they're going there because we don't have the data on that yet. So we are trying to look at some of the use patterns of the other substitutes, and we have to—one of the parts of unreasonable risk is where are the substitutes going to be and what are those risks going to be.

Sometimes the Government seems to be regulating one, and we just drive people around looking for data. We regulate one. Everybody stops using that. They go to something else. Part of the use of methylenechloride is because several years ago we decided that chlorofluorocarbons were bad, so a lot of the aerosol uses came because we banned the use of chlorofluorocarbons, and that's bad for the ozone layer.

So it doesn't do much good just to drive things around in terms of you've got to try to look at a category, and we are trying to look at a category.

Mr. VOLKMER. Now what are the neurotoxin effects of methylene chloride?

Mr. CLAY. I can either have Dr. Sette come forward and tell them—I don't know them.

Mr. VOLKMER. Dr. McMillan or Dr. Spencer, for my own——

Dr. SPENCER. Methylenechloride is a very special solvent. I think one should be rather cautious in generalizing about solvents as if they are all going to cause the same effect.

Methylene chloride is a very special solvent because it is broken down in the body to carbon monoxide, which I think both the EPA and the rest of society have learned for many, many years is a potent indirect cardio and neurotoxin.

It is quite clear—and the EPA has reviewed this—that there are additive effects from the carbon monoxide generated as a breakdown product of methylene chloride, additive effects on—to the

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carbon monoxide generated by cigarette smoke and from other sources of carbon monoxide exposure.

I suppose it would require the most elementary examination of the mixture by a school kid opening up—oh, I don't know—a 1920's textbook on occupational medicine to be aware of the threat of carbon monoxide and its effect on the brain.

I do not understand why, since we happen to have this crucial piece of information with regard to this particular solvent, because we are fully aware of the adverse health effects of carbon monoxide, why we wait so long to address whether it could possibly have any effects on heart or brain.

We've heard about liver. I don't know what the problem is with liver in relationship to the carbon monoxide metabolite. It might be a problem in relationship to some other property of the parent solvent.

It was clear-cut justification for tens of years to pay attention to this particular solvent. I might add, of course, that it is used in vast quantities and in unregulated settings, both in the domestic and professional workplace environment.

Mr. VOLKMER. People actually use it to clean their hands and things like that?

Dr. SPENCER. Well, it's used to—it has this wonderful property of evaporating very quickly, and so it's very useful for cleaning or degreasing metal parts, among a number of other uses.

It's used in coating photographic films, aerosol formulations, and in—to a great extent, as a paint stripper. And there is great concern as a painter. For example, in a closed environment with the heat on stripping paint would be exposed to substantial levels of methylenechloride which would break down in the body to carbon monoxide. There's great concern that since the brain is so peculiarly dependent upon a normal oxygen source that the presence of carboxyhemoglobin both from methylenechloride and possibly additionally from cigarette smoke might pose a serious hazard for that individual.

Mr. VOLKMER. In other words, if you're a smoker and a painter, you'd better watch out?

Dr. SPENCER. That's bad news.

Mr. VOLKMER. You're stripping; you're in bad shape.

Now, Mr. Clay, I'd like to get back—if section 4(f) included the question of neurotoxicity as one of the things to look for, would you have then done something different earlier as far as methylenechloride?

Mr. CLAY. I guess the hypothetical questions are always difficult to answer. I guess I don't know. I mean, it depends on—I know we knew about the acute neurotoxicity. We know about many chemicals are hazards; it doesn't mean we're going to go out and—regulation is a multiyear, many-agency operation the way we practice in this country today.

Methylenechloride, for example, will involve us with OSHA, will involve us with CPSC, will involve us with other parts of EPA, the Clean Air Act, probably the Clean Water Act, certainly the Pesticide Act, and what have you.

So to say, if it had been section 4(f)—if we had made a section 4(f) finding, yes, we would have done it. Would we have made the sec-

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tion 4(f) finding? I don't know. That's—the administrator makes those findings, and you'd have to predict, would it have been serious and widespread and harm humans from neurotoxicological, and I don't know—I don't know what we would have done for sure. But had we made it a section 4(f), yes, it would have gone to the top of our regulatory heap.

Mr. VOLKMER. At least you would have had a basis, would you not?

Mr. CLAY. Yes, sir. Again, it's—I'm back—hypothetical back—if we had called it a section 4(f), it certainly would have been eligible, and then it would have gone to the top of our regulatory heap and we would have been off working on it.

Mr. VOLKMER. How long did we look at asbestos?

Mr. CLAY. How long did we look at asbestos?

Mr. VOLKMER. Or formaldehyde?

Mr. CLAY. Well, formaldehyde--well, the NPR on asbestos was written in 1979. So we've been considering, contemplating the regulation of asbestos for that for—since 1979.

Formaldehyde was declared section 4(f) about a year and a half ago, something like that.

Mr. VOLKMER. So how long will it be before a decision you think will be made on methylene chloride as far as being even carcinogen ic?

Mr. CLAY. I think we believe it's a—what we call a B(2) carcinogen, the fact that it's a carcinogen in conditions of test. The final regulatory decision--it's not clear at all it will be regulated in TSCA. It could very well be regulated by OSHA. It could be regulated by CPSC, the Clean Air Act, the Ambient, the Pesticides, and what have you.

And we do have an interagency group worrying about that, but it will take some time. Rulemaking takes time. I mean we've never gone—in the best of times, rulemaking takes 2 to 3 years, and this is the first step in rulemaking.

Mr. VOLKMER. I'd like to now turn to the gentleman from California who has been very patiently waiting for me.

Mr. PACKARD. Thank you, Mr. Chairman.

Mr. VOLKMER. You can take more than the 5 minutes

Mr. PACKARD. The—let me followup on one of the questions that was asked and then addressed. If an industry does choose to use control equipment rather than testing, is there a followup procedure? Who checks, who monitors that, the use of control equipment to determine whether they're complying or whether there needs to be further testing?

Mr. CLAY. We have a compliance program at EPA which will do inspections. One of the things we require in the consent order is for them to keep records such as the—if we require respirator fit records, what have you—and we will go out and inspect those that have signed consent orders to make sure they are following.

Mr. PACKARD. The—in your statement you indicated that for 7 years now you've—our new chemical program has reviewed 5,700-some chemicals. What types of neurotoxins have you tested as among those?

Mr. CLAY. We don't do testing in the new chemical area per se. The burden is on the company to test.

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For those—for 15 chemicals, we've had—we've limited exposure because—based strictly on neurotoxicity concerns. For three of them we have the neurotoxicity testing trigger. One of the ways we have found to get away from the fact you can't afford the testing at this time, otherwise you would not make a product, is to put a trigger in a certain volume. When you reach that volume, we believe you can then afford—then you must do the testing. Those are still running.

And six people tested voluntarily at the request of EPA for neurotoxicity, so a relatively small number.

Mr. PACKARD. Should it be increased?

Mr. CLAY. Well, we believe that if you look at the record of the last several years, it is going up. So the percentage is, in fact, increasing.

Mr. PACKARD. Dr. Spencer, do you feel that the current laws are adequate to provide for the testing of substances that are neurotoxic?

Dr. SPENCER. I think it's clear from what I've said already that, since we don't require premarket testing and those scientifically proven—by those scientifically proven methods which are satisfactory, that obviously we're not doing an adequate job.

Mr. PACKARD. In Dr. Clay's testimony he indicated that EPA uses the state-of-the-art procedures and testing mechanisms. Do you feel that that's true?

Dr. SPENCER. I stand to be corrected, but my understanding is that EPA relies very heavily on the data which are submitted voluntarily by the company, and also examines the structure of the chemical and makes their best guess, but a guess nevertheless, of whether it is likely to be a potential neurotoxin or other target organ toxin.

Mr. CLAY. If I can respond to that, I don't think that's exactly the way I would characterize it. I think for the new chemical area we certainly do not have a lot of data. However, for the existing chemical area I think we are, at least among regulatory agencies, the ones that do—have developed eight particular guidelines, which is more than any other regulatory agency has. And in our existing chemical program, which can afford the testing, we are, in fact, more and more using and requiring the neurotoxicity testing.

In our volume-based determination, which we call a type B finding under section 4, our standard battery, when we're requiring the testing based just on volume, we routinely include neurotoxicity. So when we are requiring testing, we have a chance—we do, in fact, require it.

Mr. PACKARD. Dr. McMillan, there are thousands, 60 or so thousand, chemicals and compounds now in circulation, and obviously new ones are coming on in great numbers annually. How should we prioritize our testing procedures?

Dr. MCMILLAN. Well, that's a very difficult question, something the National Academy of Science struggled with over a 3-year period.

I don't think that we have anything much better to go on than what Mr. Clay has indicated. In my opinion, the first priority should go to those chemicals where the exposure is greatest and

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where we have some reason to believe that there might be neurobehavioral toxicity.

We can get the exposure data sometimes, but even there it's sometimes very difficult to get the exposure data. Some of the companies are very secretive about what they're making and how much of it they're making, and they're not really willing to let those data become public or even to go to a committee of the Academy.

The neurobehavioral toxicity testing not being in existence for most of these chemicals really doesn't give us the second part of the equation we need. We don't have that vital information on anything other than guesses about what compounds are likely to cause us trouble.

So I think the methods are there to make those guesses. We simply need to start doing it. We need to require the companies to start making some of these tests.

Mr. PACKARD. I would yield to the chairman on that point.

Mr. VOLKMER. Yes. You mentioned the recommendation of the National Academy of Sciences and how they struggled over it, and then how—my question is, What resources should we develop in order to undertake the toxicity testing that's been recommended by the National Academy of Sciences in their report?

Dr. MCMILLAN. Well, it's clear that we don't have the numbers of neurobehavioral toxicologists available to do all the testing that would be required if we were to test everything. It's just an utter impossibility—that if we made all of our graduating seniors in high schools go into neurobehavioral toxicity training and came out Ph.D.'s at the other end, it would probably take some years to develop the number of people that would be necessary to do the work.

So we have to prioritize, but at the same time that we're prioritizing what chemicals we're going to look at, I think we need to train more people. I think we need to put some money into training programs, in graduate schools, in medical schools, to develop physicians and Ph.D.'s that have special training in these particular areas, so that we have the personnel and the manpower to do the testing.

Mr. VOLKMER. If the gentleman would yield further—would you then prioritize—in other words, on the limited funding that we have, would you prioritize in the sense as to the training and education of people into this field?

Dr. MCMILLAN. I would make training a very high priority for what funds are available, but I think I would also go ahead and install some sort of behavioral toxicity testing on a broader scale than it's currently being done.

Mr. VOLKMER. Dr. Spencer, would you like to comment on it?

Dr. SPENCER. Thank you.

I would like to encourage, if you like, the EPA and other bodies to go toward the final goal of trying to understand the relationship between structure and toxicity. If this were ever possible, it would be a marvelous way to—at least to flag compounds of concern.

I've expressed the belief that we are a long way off from that laudable goal. In order to get to that goal, I believe we have to understand much more about the mechanisms by which chemical sub-

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stances affect the nervous system and the potential targets within the nervous system, of which there are many.

In order to understand the mechanisms, we don't need to institute a broad testing program. That will not solve that particular problem. We will, perhaps in a period of 10 years, get to an inventory of 20 or 30 compounds that we suspect may be neurotoxic, and some of those will prove to be so and out they go. And we will be left with 99,000 other chemicals which we scratch our head and wonder what we should be doing.

However, if we can, indeed, understand what the relationship is between chemical structure mechanisms and action on the brain and nervous system, then we stand a damned good chance of going through a large number of these agents.

How do we get at mechanisms? We get at mechanisms by the very methods that my colleague, Dr. McMillan, has described. We increase our training programs. We increase the level of scientific endeavor inquiring into the relationship between chemical exposure and brain toxicity. And we do that in academic and other environments. This is, undoubtedly, the way to go, I believe.

We will understand along the way how we can use surrogate biological systems—what I mean by that is systems other than animals—in order to develop sensitive screening methods that might fill in before we get to that laudable goal of structure activity relationships.

We will along the way utilize lower species which may be cheaper. We will utilize tissue culture methods which perhaps are more rapid, which may fill in as possible screening methods. And at the same time we will be learning a lot more about mechanisms.

That would be the way I would approach this vast problem that we have, the vastness being related to the number of agents already in place in our society and those which are coming along.

Mr. VOLKMER. Thank you very much.

I yield back to the gentleman from California. Thank you very much.

Mr. PACKARD. Dr. McMillan, you mentioned briefly the concern that companies and industry have in protecting their own products, new products particularly and patents, and so forth. That, I think, is probably a significant problem to deal with.

How should the law be changed, or should it be changed, to better protect the public from the effects of the secret and protective mechanisms of developing a new and marketing a new product? Are there some flaws in the system that we now have that permits new products to be kept under wraps, reasonably so, but still, therefore, marketed without the appropriate testing and control procedures?

Dr. MCMILLAN. Well, I think if we did some of the—a little more of the appropriate testing we wouldn't have the problem to the extent that we do. And some companies are very responsible with respect to granting this kind of information to a committee such as that of the National Academy of Sciences. Others were very much less so—that there was certain information filed on pesticides and drugs that was simply not available.

Furthermore, we have no idea of what the companies might know that was not submitted that they may have done a great deal

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more testing than what was submitted to any of the regulatory agencies, and that data is totally outside the public domain.

Mr. PACKARD. Has the history of government and other agencies in terms of protecting the companies' products and formulas from being stolen by other companies, particularly where their entire livelihood or the success of a company may depend upon the marketing of one product—they may be putting sufficient amount of research dollars into a project that, if they don't recoup, it could mean the demise of the company.

Has there been a good history or a poor history in terms of protecting the companies' secret products?

Dr. MCMILLAN. I'm not really competent to comment on that. I can give an opinion. I can understand the companies' point of view on this.

Many times they don't even want their competitors to know that they're working in a particular area, and it would be devastating perhaps for them economically for perhaps a larger company to even know of their interest in an area, much less their data. So I have some sympathy for the companies on the problem, but to what extent this type of information has become inappropriately public, I can't comment.

Mr. PACKARD. Let me look at the other side of the coin, then—that of the company and their integrity. Is there a history of companies not divulging potential difficulties or hazards with their products, even when their own testing, preliminary testing, may have uncovered some hazards or problems?

Dr. MCMILLAN. This has happened on occasion. There are—there have been many lawsuits over this, particularly with drug companies where drug companies have been accused of having some information about drug toxicity and, because of the profits from the particular drug, being reluctant to make this as rapidly available as they might.

I don't think that this is all that much of a problem. Perhaps I'm a bit naive, but I think that most of the companies, when they realize that something is causing a serious problem, do what they can to rectify the situation. I think the difficulty is in not testing in the first place and not knowing that we have a problem until it is out there in the human laboratory.

This refers back to a question that came up earlier from the chairman: is our final test system for many of these the human population that's exposed? I think it probably is, and I think we're not even doing anything there; that we don't have any mechanism involved for looking at what is happening to the human population.

We have a National Center for Toxicological Research, but that's mostly looking at predictions of what's going to happen on the basis of animal studies. But we don't even have a mechanism for evaluating what's happening in humans. We don't have a national center for clinical toxicology, for example, so that when we have a problem come up like agent orange or something like that, there's not even any place these people can go to evaluate, to be evaluated, and see if there is even substance in their claims of health deficits. And I think this is something that we need, either a national center or some sort of regional centers that people who have been

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exposed or even think that they have been exposed can go for expert evaluation.

Now what happens, as we heard from our painter this morning, is that they go around from spot to spot and physician to physician, usually the physicians having no sensitivity to chemical toxicity, being poorly trained, and lots of time and money is wasted. I think we need some mechanism to deal with this on a national level.

Mr. PACKARD. That's a very interesting comment.

Do you agree, Mr.—Dr. Clay?

Mr. CLAY. Not entirely, I don't think. One of the things I'd like to point out is that under section 8(e) of TSCA, if a company conducts a test or has other information that comes to its attention of a significant effect of any of the chemicals they produce, they are required to notify us. That's happened something like 506 times since the passage of TSCA, and about 5 of those—about 5 percent of those have been neurotoxic concerns.

What we do, then—and that's generally not confidential data because it's existing chemical data, health and safety data which cannot be claimed confidential—we, then, disseminate that widely around the Government, including NIOSH, OSHA, and others, as well as labor unions and other particular groups receive that on a regular basis.

So if the company does, in fact, do the testing and they do find significant effect, they are required by law to notify us.

Also, under section 8(c) of TSCA, which had to be implemented by a rulemaking that has only been in place about a year, if the employee has an allegation of an adverse effect, the company is required to keep records. If we then are interested in that, we can require the companies to submit those records, but they are not required to routinely do so.

The other thing that goes back to the earlier question—any chemical that is designated through us for testing by the ITC, we routinely require trigger rules under section 8(a) and 8(d) of TSCA, which requires the submission of all unpublished health and safety studies on those chemicals as well as the exposure information to the degree that they have it, including the number of workers that are exposed and types of exposure, and what have you.

Mr. PACKARD. Do those regulations apply to all sizes of companies? Supposing there are companies with only a few—10 or 12—employees, and recordkeeping of that scope is virtually——

Mr. CLAY. There is a small manufacturing exclusion which we can override if we find significant reason for doing so, but you're right, there is a—it's approximately $30 million a year annual sales that's considered a small company.

Mr. PACKARD. The hearings that I've attended on other issues—asbestosis and so forth—and listened to people like the painter this morning that have a tendency of looking at their particular work conditions as the sole problem or sole source of all of their problems when it could be a variety of other and complementing problems, too, such as tobacco, as mentioned by Dr. Spencer.

It seems that there could be a system set up that would evaluate the epidemiology and look at the results on society generally that might have a significant role to play in doing the final—or allow-

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ing people to be the final research or end product of our research, which may not be done now and may be a neglected area.

Dr. Spencer, do you have any comments on what we could do further in terms of taking human experience and synthesizing it and better using it to evaluate where we ought to go?

Dr. SPENCER. To answer that important question, I think of it at many levels. Perhaps I could start by saying that, with regard to the approach that is commonly used, namely, the volume of a particular material used as being the basis for attention, I'm not at all sure that that is the full story, because the major manufacturers rarely have cases of occupational disease. And if those high-volume materials were used in settings, other settings of major companies where good occupational hygiene was observed, those, too, would be unlikely to expose the sufficient concentrations needed to induce neurotoxic disorders.

The problem lies in the mom-and-pop industries and the settings where occupational hygiene is not a priority issue, where nurses and physicians either don't exist or they're not properly trained.

I would encourage, therefore—and I think it has been reflected earlier—an increased focus on training in occupational medicine, occupational hygiene, and the deliberate collection and searching for data from potentially exposed populations on a pseudo-epidemiological basis, nothing very fancy scientifically speaking; facilitate the collection of work experiences, if you like, to see where the patterns fall out, and collect those experiences from those companies which are greatest at risk; namely, the small companies where hygiene is not a high priority issue.

Mr. PACKARD. Let me just make one comment and then I'll close, Mr. Chairman.

The—it appears to me that one serious concern and problem we have in this whole area of occupational hazards, and even hazards in the home, which are becoming more and more a problem to government because of the lawsuits and the horrendous costs that are now becoming—that we're getting involved in, both through the legal system and through Government systems. We've got to find some solutions that are outside of simply allowing the courts to determine on emotional basis in some cases, rather than on scientific basis, the causative effects of some of these rather significant social hazards that we're experiencing.

Again, we went through last year some significant hearings on asbestosis and horror stories that were just—on both sides of the issue, both from a health position of people who have contracted the disease, but also in the legal settlements of corporations that have literally been destroyed because of having to take the brunt of the problem.

There needs to be some better solutions, and I see this becoming more and more of a compounding problem as we move—we started out in black lung and now asbestosis, and we're going to find that it goes into these chemical hazards, wastes, cleanup problems, Superfund problems.

I see this whole thing emerging as a major, major economic, judicial, and social problem, and governmental problem, because government is not excused. They're often named in these kinds of litigations because of their own inappropriate or inadequate regula-

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tory measures, and government now are becoming the deep pocket, often ends up picking up the bulk of the cost of any of these settlements and litigation that takes place.

I see this where we've got a major problem that is simply emerging now. We're struggling with some of these that I've already mentioned, but it's only emerging as a major problem. I would be very interested in your comments on what we ought to do to try to shortcircuit this trend that we're moving into, that I think is going to become a major, major problem.

If you have any quick comments—I think I've taken more of my time again—but if you have any comments on that, I'd be interested in closing on those comments.

Dr. McMillan.

Dr. McMillan. Well, I would simply reiterate some of the points that Dr. Spencer has made—that I think the training of more experts in the area is very important. I think getting at some of the mechanisms underlying the toxicity is very important.

We worry an awful lot about how much this is going to cost. We don't really know, though, but what, if we make this effort, if it isn't going to be quite cost-effective in the long run; that if you can interrupt some of these problems back at the source and not have to deal with the medical treatment of the exposed population, the hours that are lost in productivity of the worker who can't work, the human tragedy that's involved—who's to say that much bigger expenditure on controlling these chemicals wouldn't be cost-effective in the long run, although it would maybe hurt a great deal to do it in the short term? We may be being penny wise and pound foolish.

Mr. Packard. That's very true. The other part of the problem, however, is that many of these things do not manifest themselves until literally decades after the problem has existed. So you may not even be aware that there is a problem out there, and the researh may not uncover that problem.

Dr. Clay, do you have any comments in closing?

Mr. Clay. No. I would agree with you that the complexity of the problem is just immense. The synergism, the long delay time. Particularly the ones you mentioned happened to be unique, and there was some sort of disease that was a marker for a particular exposure, but for most of these, these are not these cause-effects that we can—from any number of ways, it's a very complex problem. Society has to struggle with it.

Part of the problem seems to be the question of who pays. Do the companies pay now; does society pay for medical costs later, and what have you? But that's one for the Congress.

Mr. Volkmer. I have a few things I'd like to close—before I close.

Dr. Spencer, BHMH, what is that actually? Can you tell me?

Dr. Spencer. It's a catalyst. The scientific name is 2-t-butylozo-2-hydroxy-5-methylhexane. It's a plastic-forming catalyst which was used in the manufacture of reinforced bathtubs.

Mr. Volkmer. OK. Now is it cancer causing, carcinogenic? Do we know?

Dr. Spencer. I believe it's untested.

Mr. Volkmer. Untested? All right.

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But it was in existence prior to 1976, so it's in the inventory; is that correct, as I understand the testimony?

Mr. CLAY. Yes, sir. The inventory was as of 1977 data.

Mr. VOLKMER. Right. Now let's say that I'm a person that somebody would say is irresponsible and I'd like to get into the manufacturing business, and I decide I'm going to go ahead and use it. I'm in manufacturing; nobody's going to stop me, are they?

Mr. CLAY. I don't know whether OSHA controls it or not. I mean, that would be——

Mr. VOLKMER. Well, if OSHA would come in and it has significant risk, it's got to have cancer, be carcinogenic. OSHA hasn't really even developed the standards for its toxicity, has it? So I'd just go out and do it anyway.

Of course, I've got a corporate structure and, therefore, liability is to that corporation. Five years from now a bunch of people are sick and can't work anymore and everything, and they sue the corporation, and the corporation is defunct. Nothing stops me. Is that——

Mr. CLAY. In the absence of an OSHA standard, certainly EPA is not stopping you right now from that particular scenario.

Mr. VOLKMER. I don't know anybody in the Government that's going to stop me. I'm going to go ahead and do it. So that's something I think we ought to realize.

No. two, Mr. Clay, I know this is not—I just want to—I don't know if you agree with these figures, and it's not your responsibility or fault or anything else; I want to make clear about that—but let me give you some figures here that shows that EPA's total operating budget, total funding, is over $1 billion, of course; right?

Mr. CLAY. Yes, sir.

Mr. VOLKMER. Total EPA?

Mr. CLAY. Uh-huh.

Mr. VOLKMER. And it has here budget for all toxicology research, a little over $32 million.

Mr. CLAY. That's approximately correct, sir; yes.

Mr. VOLKMER. And budget for neurobehavioral toxicology research, not quite $3 million.

Mr. CLAY. I have slightly over $3 million, but in the order of magnitude of $3 million.

Mr. VOLKMER. Order of magnitude of $3 million.

Any possibility of having an improvement in that?

Mr. CLAY. Budget figures are very complex, and it's up to the Administrator to allocate the amount of money that he has. As you pointed out, these are moneys being spent in the Office of Research and Development—I guess I'm not—the question is, Are you going to spend it on this versus something else, biotechnology or what have you?

Mr. VOLKMER. It's going to come out of somebody else's pocket if it goes here?

Mr. CLAY. That's right. The probability of expanding the budget is not very high, so you're talking about coming from—the system has allocated about that amount of money.

Mr. VOLKMER. OK. Before we conclude, I would like to have Dr. Sette—is that it, Sette?

Mr. CLAY. Yes.

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Mr. VOLKMER. Could he take the chair there?

Mr. CLAY. Sure.

Mr. VOLKMER. I have a couple of questions I'd like to ask Dr. Sette.

Dr. SETTE. Good morning.

Mr. VOLKMER. And I'd like to know, first, are the EPA guidelines scientifically valid as tests industry could use to screen chemicals?

Dr. SETTE. We certainly do believe that they are scientifically valid. They were written in some cases by Dr. Levine and myself; in other cases, by members of the Office of Research and Development.

They were then sent for outside review by members of industry and academia. Both of the panel members have reviewed one or more of the neurotoxicity guidelines. They were, in part, designed on the basis of their wide acceptance and on the basis of previous recommendations of committees of the National Academy of Sciences, and so they were not original in that regard and are, therefore, widely accepted by the scientific community, in the chemical industry as well as in the academic and research community.

Mr. VOLKMER. So my answer, to get back to the question, is yes?

Dr. SETTE. Yes. Yes, sir.

Mr. VOLKMER. OK. Now does the—if you know—does the Pesticide Division of EPA use the same guidelines you use in toxic substances as far as neurotoxicity?

Dr. SETTE. The Office of Pesticides Program makes use of two of the eight guidelines. Those two guidelines were designed specifically for organophorphorous esters. They thus far have not adopted any of the remaining guidelines of the Office of Toxic Substances.

We have, however, very recently initiated a dialog with the pesticides people to explore their use of these guidelines.

Mr. VOLKMER. Could you use additional help, additional staff?

Dr. SETTE. Sir—— [Laughter.]

Mr. VOLKMER. I don't know whether you ought not answer or just no comment; just say, "No comment."

Dr. SETTE. The Administrator makes——

Mr. VOLKMER. I don't want to put you on the spot.

Dr. SETTE [continuing]. Makes that decision, but if I were to advise the Administrator on that topic, I would have to say yes.

Mr. VOLKMER. OK.

I want to thank everyone, all the panelists we've had here today and the witnesses, for providing this committee with thought-provoking presentation on the health effects of neurotoxins, what we could and should be doing to predict and prevent these effects, and especially the idea, the thought—I guess it has some validity—that we are looking at a possible causation for such things as Parkinson's disease, Alzheimer's disease, or other things in the realm of possibility, which I hadn't given a thought to.

Your testimony is a valuable contribution to this committee's efforts to address this problem. I sincerely want to thank you all.

Tomorrow the committee will hear testimony concerning our workplace exposure levels, the technologies we use to control exposure, and the ways in which we warn workers of the hazards they face every day.

Again, I want to thank all of you for coming.

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The committee will now be in recess. We will reconvene tomorrow morning at 9 o'clock in this room.

Thank you very much.

[Whereupon, at 12:41 p.m., the subcommittee recessed, to reconvene the following day, Wednesday, October 9, 1985, at 9 a.m.]

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NEUROTOXINS AT HOME AND IN THE WORKPLACE

WEDNESDAY, OCTOBER 9, 1985

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT,
Washington, DC.

The subcommittee met, pursuant to recess, at 9:12 a.m., in room 2325, Rayburn House Office Building, Hon. Harold L. Volkmer (chairman of the subcommittee) presiding.

Mr. VOLKMER. The Subcommittee on Investigations and Oversight will come to order.

Today we are continuing the hearings that we began yesterday on neurotoxins. And each of us are exposed to various kinds of chemicals every day. Many of these chemicals are harmless and help make our lives easier, safer, or healthier. However, there are more and more chemicals in our society that threaten our health and our enjoyment of life.

The public is well aware of the dangers of chemicals that cause cancer, but there is a larger class of chemicals that pose a grave danger to our health. These chemicals, called neurotoxins, poison our nervous system and can permanently damage our capacity to feel, remember, think, and act.

Yesterday at our hearing we learned that neurotoxins are found in numerous household substances such as perfumes, paint strippers, glues, drugs. We discussed how scientists have devised tests that can predict which chemicals may be neurotoxic.

Most importantly, we learned that there is a great need for testing and regulation of these chemicals by the Government agencies charged with protecting the health of the public at home and at work.

Today we take a special look at the hazards of neurotoxins in the workplace. We will examine whether OSHA, the agency responsible for protecting worker health, is protecting the millions of workers who are exposed to dangerous chemicals every day.

We will also hear from industry and union representatives how we should warn and train workers to deal with these chemicals.

One thing is certain: the dangers from neurotoxins are real. Ignoring these dangers will not make them go away. Excuses and explanations to justify regulatory inaction will also not make them go away.

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We can address and solve the dangers of neurotoxins if we have the will to do so. We hope these hearings will help create the will to solve this problem.

Our panel today is composed of Dr. Edward Baker, National Institute of Occupational Safety and Health; Mr. Patrick R. Tyson, Assistant—Acting Assistant Secretary, Occupational Safety and Health Administration; and Mr. Karl Kronebusch—is that close enough?

Mr. KRONEBUSCH. Close enough.

Mr. VOLKMER. All right; and Mr. Mike Gough—Gough?

Mr. GOUGH. Gough.

Mr. VOLKMER. Office of Technology Assessment, all from Washington, DC.

Gentlemen, all of your statements will be made a part of the record at the point in the record when you testify. You may either review that statement in full or summarize, however you so desire.

We'll begin with Dr. Baker.

STATEMENT OF DR. EDWARD L. BAKER, ASSISTANT DIRECTOR, NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH, CENTERS FOR DISEASE CONTROL, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. BAKER. Thank you very much, Mr. Chairman.

I would like to summarize the material that's been provided to you and to touch on some points that I think are highlights in the material that we provided, and also indicate why I think it's important and relevant to workers in the country that this problem be adequately considered.

I'm particularly appreciative of the fact that the committee has actually taken interest in an area which has been generally neglected in the general area of scientific concerns. It's an area of research that I've been involved in for a number of years, and it's particularly gratifying to me, approximately 1 month after coming to work for NIOSH, to find that this committee has taken this issue on directly.

With me today are Dr.—or Mr. Richard Lemen, who is Director of our Division of Standards Development and Technology Transfer. He will be assisting me in responding to some of the questions that will be raised. I would also like to mention two other professionals within NIOSH, Dr. Barry Johnson and Dr. Kent Anger, who are world-renown experts in the field of neurotoxicology. I think we're fortunate in NIOSH in having the quality of scientists that we do have within the agency in attempting to deal with the broad spectrum of problems that exist.

According to various estimates, we would estimate that from 10 to 25 percent of the chemicals that are used in the workplace do have neurotoxic properties. These include chemicals that may be used in small industries, in large industries, in hospitals, in factories, in a variety of work settings across the country.

To give you an example of a typical patient, I would like to describe an individual that I saw recently who works with neurotoxic chemicals in a job building boats. His particular exposure was to styrene. And after working with these materials for approximately

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7 years, he developed significant memory problems, mood difficulties, irritability, and he found that he had lost interest in a lot of the activities that he normally engaged in in his personal life.

On seeing him, it was clear to me that he did have evidence of neurotoxicity, and I advised him to change his job. The problem that he was then confronted with was wanting to change into another job, and he particularly was interested in becoming a locksmith, but he couldn't learn the new material necessary to become another profession. He would read the manuals but he couldn't recall the actual details of the job, and, therefore, his capacity to actually change out of a hazardous job into a less hazardous job was interfered with because of the effects that the chemicals had had on his brain.

I'm recalling how important memory is for all of us. My father was actually a Member of Congress in the past, and I was always impressed with his ability to remember people's names and to connect them with certain events in their lives. He could go up to people in the street and he seemed to have an uncanny ability, which many people do in political life, to actually remember people and associate them with certain kinds of things.

One of the things that neurotoxic chemicals do is to impair our ability to learn associations, to associate one thing with another. That's a very common kind of practice that we all engage in in mental activities from day to day.

We have used this kind of clinical information that I just described to develop newer kinds of tests that allow us to detect early on the damaging effects of chemicals on the body.

One project that NIOSH is currently involved in and one in which I was involved when I was at Harvard University was a project designed to use computer testing to evaluate the ability of people's minds to function, particularly in settings where they're exposed to neurotoxic chemicals.

NIOSH is a large-scale project that involves cooperation with scientists all over the world, involves the World Health Organization in trying to come up with newer methods for detecting neurotoxicity early on.

In that context, as was mentioned in the prepared testimony, NIOSH has, with the World Health Organization, organized a number of international meetings bringing scientists in from Europe and other parts of the world to discuss these issues. And as a result of that, I feel like that our scientists within the agency are as up to date as any in this country or abroad on the issues that are relevant to the concerns.

To summarize, I think that our involvement in the area of neurotoxicity is important for some of the reasons the chairman mentioned in his opening remarks. These chemicals affect people's daily lives. They cause them to have acute illness. It interferes with their ability to function on the job. Certainly people are having greater accidents as a result of the effect of neurotoxins on their activities.

We are particularly concerned that chronic exposure to toxic chemicals may have long-terms effects. Some people speculate that neurotoxic chemicals may actually accelerate the process of aging, and that people may age more rapidly as a result of this exposure.

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I was reading an old textbook from the earlier part of this century yesterday in preparing a lecture, and people were describing a person who was 40 years old who had worked with lead all of his life, and he had the evidence of an older man, 70 or 80 years of age, as a result of this continued exposure.

Others along this line suspect that diseases such as Alzheimer's disease may in some way be contributed to by the presence of neurotoxins in the work environment.

What are we to do? I think that it's very easy for us to say that more research is needed, and I'm sure you've heard that from many people already speaking to you earlier this—in yesterday's talks.

One of the things that needs to be done more and is being done to some extent is—are programs to educate workers and management about the hazards of chemicals in the workplace.

One particular program that I'd like to mention is one that the painters' union and the paint industry have put together to educate workers to the hazards of paint substances. This program I think is a model one. You'll be hearing it described later on by Mr. Wolford and some other people involved in the project from the industry side, and I think it's one that can be generalized to many other industries.

In addition to better education, clearly we need to utilize better methods of control that are already known for controlling these substances. It's a significant national problem.

Again, I appreciate the opportunity to talk with you today, and I'm particularly pleased that your committee is considering this issue.

Thank you very much.

[The prepared statement of Dr. Baker follows:]

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TESTIMONY OF EDWARD L. BAKER, JR., M.D., M.P.H., ASSISTANT DIRECTOR, NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH, CENTERS FOR DISEASE CONTROL, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

I am Dr. Edward L. Baker, Assistant Director of the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control, in the Department of Health and Human Services. I appreciate this opportunity to discuss the activities of NIOSH concerning neurotoxic substances in the workplace. With me today from the Institute is Mr. Richard A. Lemen, Director, Division of Standards Development and Technology Transfer.

It has long been recognized that certain substances found in workplace environments can adversely affect the nervous systems of workers. These have been labeled neurotoxic substances. Some of these substances, like inorganic lead and other metals, have been known since ancient times to be toxic. Others, like methyl n-butyl ketone (an industrial solvent) and chlordecone (an insecticide) were only recently identified as neurotoxic after workers' health had been seriously impaired. Still others were found to be neurotoxic in toxicologic tests with laboratory animals. We do not know the exact number of workplace chemicals that are neurotoxic, but many heavy metals, solvents, pesticides, and noxious gases are recognized to possess neurotoxic properties. Some of the adverse health effects that have been attributed to excessive exposure to various neurotoxic substances are encephalopathy (disorders of the brain) from metals, peripheral polyneuropathies (diseases of the peripheral nerves) from metals and solvents, psychiatric conditions (mood and cognitive changes) from select solvents, and impairments from several neurotoxic substances to memory, reaction time, coordination, and sensory functions.

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The effects of neurotoxic chemicals on the nervous system are determined by properties of the chemical itself, the exposure experience (duration, frequency, and level), and personal factors (such as age, weight, and health status) of the person exposed. Also, the effects of neurotoxic substances in the workplace can often be exacerbated by such factors as smoking history, drug use, and alcohol consumption. Short-term, high exposure can result in severe neurologic damage and, in extreme cases, death. Acute poisonings from lead, carbon monoxide, and mercury, can be life threatening. Although acute exposure events still occur, improvements in industrial hygiene and engineering controls have reduced their occurrence. The greater concern is now 1) to identify those chemicals that have neurotoxic properties, 2) to assess the effects on human health of chronic exposure to known neurotoxic substances, and 3) to develop and disseminate recommendations for preventing exposure to these substances. NIOSH has been active in all these areas.

The Institute has been conducting research on neurotoxic substances since its establishment in 1971 and has provided research grants to several laboratories for their study of neurotoxic substances. In some studies, we have used animal models to test or identify occupational chemicals that may affect the animals' central or peripheral nervous systems or modify the animals' behavior. These studies are important because the animals can be studied under precise exposure regimens. That is not practical or desirable, of course, in actual occupational settings.

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NIOSH investigators have also conducted many studies of workers occupationally exposed to known, or suspected, neurotoxic substances. These studies have often been conducted through our health hazard evaluation (HHE) program--in which we evaluate workplace conditions at the request of employers or employees and provide recommendations to alleviate any safety and health problems that might be found. The HHE program is an important way of identifying newly developing occupational safety and health problems. NIOSH conducts approximately 500 of these evaluations per year. Many involve exposures to neurotoxic substances or workers' complaints about symptoms compatible with neurotoxicity. For HHEs completed in FY 1984, we reviewed 134 reports that had significant information on health effects and/or overexposures. Of these, 34 (25%) dealt with reported or documented neurotoxic effects and/or exposures to known neurotoxins. For FY 1985 (through the third quarter), these numbers were 97 and 36 (37%), respectively.

We conduct other studies of workers as part of our programmatic research on select groups of chronically exposed workers (e.g., fumigators and rayon workers) for signs and symptoms of neurotoxicity. All these field studies employ medical examinations of the workers; administration of work history, personal, and symptom questionnaires; and objective tests including measures of central and peripheral nervous system functioning, psychologic variables (affect), and behavioral indices (performance on structured psychometric tests). The Institute's research, as well as that from other research groups, has now revealed that some neurotoxic substances can adversely affect the human nervous system at exposure levels that are below previously established occupational standards. Some examples are inorganic lead, styrene, carbon disulfide, carbon monoxide, chlordecone, and methyl n-butyl ketone.

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NIOSH has employed a variety of tests from the fields of clinical neurology, neurophysiology, and psychology to investigate adverse health effects in workers resulting from exposure to known or suspected neurotoxic substances. The clinical methods consist of a standard neurologic examination of reflexes, peripheral nerves, and the central nervous system; supplemented by neurophysiologic tests of nerve conduction velocities of peripheral nerves and electromyography (electrical activity in muscle). Methods and tests from psychology have included assessment of memory, reaction time, coordination, sensory and motor function, and affect (mood). Often these methods and tests must be modified for use in field studies. The complexities of the human nervous system and human behavior make test development and application difficult. This is especially true for health monitoring programs where the stability over time of neurologic and behavioral measures becomes most important. But progress is being made, and I wish to describe two recent advances in the development of neurologic and behavioral tests intended to evaluate or screen workers for signs of neurotoxic effects.

In 1983 in conjunction with the World Health Organization, we convened an international workshop to assess neurobehavioral methods for use in occupational health. From this meeting came an agreement on a battery of neurobehavioral tests that were recommended for application in field studies, particularly in situations where the instruments and testing methods must be kept simple. These tests measure such functions as memory, coordination, affect (mood), vision, and cognition. We are now evaluating these tests to determine their efficacy in health surveillance programs. This work should be completed in two years.

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A second area of methods development concerns computer-based neurobehavioral tests. Tests taken from clinical neuropsychology or experimental psychology have been adapted for computer presentation to the persons being evaluated. This approach holds great promise for health surveillance, but additional research is needed to verify their efficacy. NIOSH is conducting research to measure the effectiveness of computer-based neurobehavioral tests. The results from our endeavors, along with those from other laboratories, should soon give us an idea of the usefulness of these tests in workplace health monitoring programs.

Even with all the research being done on neurotoxic substances, results of these efforts can only be effective in protecting workers if they are applied in the workplace to reduce and prevent occupational health hazards. In this regard, NIOSH disseminates its findings 1) to recommend standards to regulating agencies (i.e., the Occupational Safety and Health Administration [OSHA] and the Mine Safety and Health Administration [MSHA]), 2) to inform the public of identified problems and their solutions, and 3) to share information with other scientists and organizations involved in improving workplace conditions. Since the establishment of NIOSH 14 years ago, we have recommended control in the workplace for 67 substances based on evidence of neurotoxicity (Table 1). In addition we have published in excess of 100 journal articles, book chapters, and reports on neurotoxic substances.

As you may know, NIOSH in 1982 developed a suggested list of "Ten Leading Work-Related Diseases and Injuries," based on the severity, the frequency of occurrence, and the amenability to prevention of each condition. Neurotoxic disorders appear as one of the conditions on that list (Table 2). As part of

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our dissemination effort, we convened a National Symposium on the Prevention of Leading Work-Related Diseases and Injuries, in May of this year, to focus attention and to provide a forum for discussion of the first five conditions on our list. We are now planning a second symposium for October 1986, covering the last five conditions on the list, including neurotoxic disorders. At this next symposium, we will introduce a proposed prevention strategy for neurotoxic disorders in the workplace. Following the pattern of our earlier strategies, it will outline the research needs and the action necessary to prevent neurotoxic disorders in the workplace. We look forward to an interaction and exchange of information within the occupational safety and health community on this important topic.

"The Dormant Standards"

As the subcommittee requested in its letter of invitation, the following is a summary of NIOSH involvement with the OSHA "dormant standards" project. In the fall of 1983, OSHA requested that NIOSH review current information on 117 potential occupational hazards for which OSHA rulemaking had not been completed. This list is commonly referred to as the "dormant standards." Of the 117 potential hazards on the list, 115 were chemical substances and 2 were processes (abrasive blasting and eye and cutaneous hazards). OSHA requested that we review only the chemical substances. Our purpose in evaluating the information on the dormant standards was to identify substances for which, in our opinion, sufficient information exists to support continued rulemaking.

After completing our evaluation, we were able to place each of the 115 substances in one of three groups. The first group contains 51 substances for which information indicates the existing OSHA standard is not sufficiently

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protective and rulemaking should proceed. The second group contains 18 substances for which we believe rulemaking should be deferred pending the outcome of ongoing research. Information on the 46 remaining substances did not indicate a need to pursue rulemaking, either because the information is insufficient or because the current OSHA standard appears to provide adequate worker protection.

Many substances in the first group had been the subjects of criteria documents previously transmitted to OSHA. A review of these 51 substances reveals that 35 are associated with neurotoxic disorders. Table 1 identifies these substances.

It is hard to predict the consequences in the workplace if OSHA does not accept the NIOSH recommendations for these substances, since many NIOSH recommendations are often used by industry as their own internal standards when developing programs for occupational safety and health. It may well be that similar actions will be taken following the dissemination of our recommendations on the "dormant standards."

Thank you for the opportunity to describe NIOSH activities concerning neurotoxic substances in the workplace. I will be happy to answer your questions.

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Table 1. Standards for Chemicals or Groups of Chemicals Producing Neurotoxic Effects

Chemical	Document Type*	NIOSH Recommendation (REL)#	OSHA Standard (PEL)#
1) Acetylene	Criteria document	No exposure | 2,500 ppm# (2,662 mg/m^3)	2,500 ppm (10% of lower explosive limit)
2) Acrylamide	Criteria document	0.3 mg/m^3 TWA#	0.3 mg/m^3 8-hr TWA (skin)
3) Acrylonitrile	Criteria document	1 ppm 8-hr TWA; 10 ppm ceiling (15 min) (skin)	2 ppm, 8-hr TWA; 10 ppm ceiling (15 min) (skin)
4) Aldrin/Dieldrin	Special hazard review	Lowest reliably detectable level; 0.15 mg/m^3 TWA by NIOSH validated method	0.25 mg/m^3, 8-hr TWA (skin)
5) Alkanes pentane hexane heptane octane	Criteria document	All are TWA values: pentane: 120 ppm (350 mg/m^3) hexane: 100 ppm (350 mg/m^3) heptane: 85 ppm (350 mg/m^3) octane: 75 ppm (350 mg/m^3) Mixtures not to exceed 350 mg/m^3 TWA	pentane: 1,000 ppm (2,950 mg/m^3), n-hexane: 500 ppm (1,800 mg/m^3), n-heptane: 500 ppm (2,000 mg/m^3), octane: 500 ppm (2,350 mg/m^3), 8-hr TWA

* Criteria documents: exhaustive reviews of a subject concluding with specific recommendations for standards, including quantitative recommended exposure levels (REL) where appropriate
Current intelligence bulletins (CIB): short reviews summarizing new scientific findings and providing an interpretation of their implications for prevention
Special hazard reviews: complementary and support reviews that analyze and document health problems associated with given industrial chemicals, processes, or physical agents and recommend the implementation of engineering controls and work practices to ameliorate these problems.

# REL = recommended exposure limit
PEL = permissible exposure limit
ppm = parts per million
ppb = parts per billion
TWA = time weighted average

★ Substances from the dormant standards

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Chemical	Document Type	NIOSH Recommendation (REL)	OSHA Standard (PEL)
6) Allyl chloride*	Criteria document	1 ppm (3.1 mg/m^3) TWA; 3 ppm (9.3 mg/m^3) ceiling (15 min)	1 ppm (3 mg/m^3), 8-hr TWA
7) Anesthetic gases	Criteria document	Halogenated anesthetic agents: 2 ppm ceiling (1 hr); nitrous oxide: 25 ppm TWA during period of use	None for substances when used as anesthetic agents
8) Arsenic, inorganic	Testimony to OSHA	2 ug As/m^3 ceiling (15 min)	10 ug/m^3, 8-hr TWA
9) Arsine*	CIB #32	2 ug As/m^3, ceiling (15 min)	0.2 mg/m^3 (0.05 ppm), 8-hr TWA
10) n-Butyl alcohol*	None	No NIOSH REL	100 ppm (300 mg/m^3), 8-hr TWA
11) Cadmium*	CIB #42	Reduce exposure to lowest feasible level based on potential as a carcinogen	Fume: 0.1 mg/m^3, 8-hr TWA; 0.3 mg/m^3 ceiling; Dust: 0.2 mg/m^3, 8-hr TWA; 0.6 mg/m^3 ceiling
12) Carbaryl	Criteria document	5 mg/m^3 TWA	5 mg/m^3, 8-hr TWA
13) Carbon dioxide	Criteria document	10,000 ppm (18,000 mg/m^3) TWA; 30,000 ppm (54,000 mg/m^3) ceiling (10 min)	5,000 ppm (9,000 mg/m^3), 8-hr TWA
14) Carbon disulfide	Criteria document	1 ppm (3 mg/m^3) TWA; 10 ppm (30 mg/m^3) ceiling (15 min)	20 ppm, 8-hr TWA; 30 ppm acceptable ceiling; 100 ppm maximum ceiling (30 min)
15) Carbon monoxide*	Criteria document	35 ppm (40 mg/m^3), 8-hr TWA; 200 ppm (229 mg/m^3) ceiling (no minimum time)	50 ppm (55 mg/m^3), 8-hr TWA

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Chemical	Document Type	NIOSH Recommendation (REL)	OSHA Standard (PEL)
16) Carbon tetrachloride*	Criteria document	2 ppm (12.6 mg/m^3) ceiling 45 liter sample (60 min)	10 ppm, 8-hr TWA; 25 ppm acceptable ceiling; 200 ppm maximum ceiling (5 min in 4 hrs)
17) Chlorine	Criteria document	0.5 ppm (1.45 mg/m^3) ceiling (15 min)	1 ppm (3 mg/m^3) ceiling
18) Chlorobenzene*	None	No NIOSH REL	75 ppm (350 mg/m^3), 8-hr TWA
19) Chloroform*	Criteria document	2 ppm (9.78 mg/m^3) ceiling 45 liter sample (60 min)	50 ppm (240 mg/m^3) ceiling
20) Chloroprene	Criteria document	1 ppm (3.6 mg/m^3) ceiling (15 min)	25 ppm (90 mg/m^3), 8-hr TWA
21) Coal gasification	Criteria document	NIOSH RELs or OSHA PELs for specific hazards are applicable	
22) Cresol	Criteria document	2.3 ppm (10 mg/m^3) TWA	5 ppm (22 mg/m^3), 8-hr TWA (skin)
23) Cyclohexanone*	Criteria document (Ketones)	25 ppm (100 mg/m^3) TWA	50 ppm (200 mg/m^3), 8-hr TWA
24) DDT	Special hazard review	Lowest reliably detectable level; 0.5 mg/m^3 TWA by NIOSH-validated method	1 mg/m^3, 8-hr TWA (skin)
25) 1,2-Dichloroethane* (ethylene dichloride)	Criteria document	1 ppm (4 mg/m^3) TWA; 2 ppm (8 mg/m^3) ceiling (15 min)	50 ppm, 8-hr TWA; 100 ppm acceptable ceiling; 200 ppm maximum ceiling (5 min in 3 hrs)
26) Dibromochloropropane	Criteria document	10 ppb (0.1 mg/m^3) TWA	1 ppb, 8-hr TWA; eye and skin contact to be avoided

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Chemical	Document Type	NIOSH Recommendation (REL)	OSHA Standard (PEL)
27) Diisocyanates	Criteria document	Each equivalent to 5 ppb TWA and 20 ppb ceiling. All values given in ug/m^3 and all ceiling values for 10 min; toluene diisocyanate (TDI) 35 TWA, 140 ceiling; diphenylmethane diisocyanate (MDI): 50 TWA, 200 ceiling; hexamethylene diisocyanate (HDI): 35 TWA, 140 ceiling; naphthalene diisocyanate (NDI): 40 TWA, 170 ceiling isophorone diisocyanate (IPDI): 45 TWA, 180 ceiling; dicyclohexylmethane 4,4'-diisocyanate (hydrogenated MDI): 55 TWA, 210 ceiling; other diisocyanates also to be controlled to 20 ppb ceiling and 5 ppb TWA	TDI: 0.02 ppm (0.14 mg/m^3) ceiling; MDI: 0.02 ppm (0.2 mg/m^3) ceiling
28) Dinitro ortho cresol	Criteria document	0.2 mg/m^3 TWA	0.2 mg/m^3, 8-hr TWA (skin)
29) Epichlorohydrin*	CIB #30 (1978)	Minimize occupational exposure	5 ppm (19 mg/m^3), 8-hr TWA
30) 2-Ethoxyethyl acetate*	CIB #39 (1983)	Minimize occupational exposure	100 ppm (510 mg/m^3), 8-hr TWA
31) Ethylene dibromide	Testimony to OSHA	45 ppb (0.38 mg/m^3); 8-hr TWA; 0.13 ppm (1 mg/m^3) ceiling (15 min)	20 ppm, 8-hr TWA; 30 ppm acceptable ceiling; 50 ppm maximum peak (5 min)
32) Formaldehyde	CIB # 34	Limit exposure to lowest feasible level	3 ppm, 8-hr TWA; 5 ppm acceptable ceiling: 10 ppm maximum ceiling (30 min)

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Chemical	Document Type	NIOSH Recommendation (REL)	OSHA Standard (PEL)
33) Furfuryl alcohol	Criteria document	50 ppm (200 mg/m^3) TWA	50 ppm (200 mg/m^3), 8-hr TWA
34) Glycidyl ethers allyl glycidyl ether (AGE), n-butyl glycidyl ether (BGE), diglycidyl ether (DGE), isopropyl glycidyl ether (IGE), phenyl glycidyl ether (PGE)	CIB #29	All are ceiling values (15 min) in ppm (mg/m^3); AGE: 9.6 (45), BGE: 4.4 (30), DGE: 0.2 (1), IGE: 50 (240), PGE: 1 (5)	All values in ppm (mg/m^3) AGE: 10 (45) ceiling; BGE: 50 (270), 8-hr TWA; DGE: 0.5 (2.8), 8-hr TWA; IGE: 50 (240), 8-hr TWA PGE 10 (60), 8-hr TWA
35) Heptane*	Criteria document (Alkanes)	85 ppm (350 mg/m^3) TWA	500 ppm (2,000 mg/m^3), 8-hr TWA
36) Hexone* (methyl isobutyl ketone)	Criteria document (Ketones)	50 ppm (200 mg/m^3) TWA	100 ppm (410 mg/m^3), 8-hr TWA
37) Hot environments	Criteria document	Action levels: 79 F WBGT (men) 76 F (women); sliding scale limits for unimpaired mental function	None
38) Hydrazines	Criteria document	All are 120 min ceiling values in ppm (mg/m^3); hydrazine: 0.03 (0.04), 1,1-dimethyl hydrazine: 0.06 (0.15), phenyl hydrazine: 0.14 (0.6);methyl hydrazine: 0.04 (0.08)	All values in ppm (mg/m^3) hydrazine 1 (1.3), 8-hr TWA; 1,1-dimethyl hydrazine: 0.5 (1.0), 8-hr TWA; phenyl hydrazine 5 (22), 8-hr TWA; methyl hydrazine 0.2 (0.35) ceiling
39) Hydroquinone*	Criteria document	440 ppb (2 mg/m^3) ceiling (15 min)	2 mg/m^3, 8-hr TWA

WBGT = Wet bulb globe temperature

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Chemical	Document Type	NIOSH Recommendation (REL)	OSHA Standard (PEL)
40) Isopropyl alcohol*	Criteria document	400 ppm (984 mg/m^3) TWA; 800 ppm (1,968 mg/m^3) ceiling (15 min)	400 ppm (980 mg/m^3), 8-hr TWA
41) Ketones - 12 separate	Criteria document	All are TWA values in ppm (mg/m^3); acetone: 250 (590) methylethyl ketone: 200 (590) methyl n-propyl ketone: 150 (530), methyl n-butyl ketone: 1 (4),methyl n-amyl ketone: 100 (465), methyl isobutyl ketone: 50 (200), methyl isoamyl ketone: 50 (230), diisobutyl ketone: 25 (140), cyclohexanone: 25 (100), mesityl oxide: 10 (40), diacetone alcohol: 50 (240), isophorone: 4 (23)	All are 8-hr TWA values in ppm (mg/m^3); acetone: 1,000 (2,400); methyl ethyl ketone: 200 (590), methyl n-propyl ketone: 200 (700), methyl n-butyl ketone: 100 (410), methyl n-amyl ketone: 100 (465), methyl isobutyl ketone: 100 (410), methyl isoamyl ketone: none, diisobutyl ketone: 50 (290), cyclohexanone: 50 (200), mesityl oxide: 25 (100), diacetone alcohol: 50 (240), isophorone: 25 (140)
42) Lead, inorganic	Criteria document	100 ug/m^3 TWA; air level to be maintained so that worker blood lead remains _ 60 ug/100g	50 ug/m^3, 8-hr TWA; over 8-hr exposure to be determined by formula
43) Malathion	Criteria document	15 mg/m^3 TWA	15 mg/m^3, 8-hr TWA
44) Mercury, inorganic*	Criteria document	0.05 mg/m^3, 8-hr TWA	0.1 mg/m^3 acceptable ceiling
45) Mesityl oxide*	Criteria document (Ketones)	10 ppm (40 mg/m^3) TWA	25 ppm (100 mg/m^3), 8-hr TWA
46) 2-Methoxyethyl acetate*	CIB #39	Minimize occupational exposure	25 ppm (120 mg/m^3), 8-hr TWA
47) Methyl alcohol*	Criteria document	200 ppm (262 mg/m^3) TWA; 800 ppm (1,048 mg/m^3) ceiling (15 min)	200 ppm (260 mg/m^3), 8-hr TWA

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Chemical	Document Type	NIOSH Recommendation (REL)	OSHA Standard (PEL)
48) 5-methyl-3-heptanone*	None	No NIOSH REL	25 ppm (130 mg/m^3), 8-hr TWA
49) Methyl iodide*	CIB #43	Reduce exposure to lowest feasible level	5 ppm (28 mg/m^3), 8-hr TWA
50) Methyl parathion	Criteria document	0.2 mg/m^3 TWA	None
51) Methylene chloride	Criteria document	75 ppm (261 mg/m^3) TWA; 500 ppm (1,740 mg/m^3) ceiling (15 min) to be lowered in presence of carbon monoxide	500 ppm, 8-hr TWA; 1,000 ppm acceptable ceiling; 2,000 ppm acceptable maximum peak for 5 min in any 2-hr period above the acceptable ceiling for an 8-hr shift
52) Nitriles - 10 separate	Criteria document	All are TWA values in ppm (mg/m^3); acetonitrile: 20 (34), n-butyronitrile: 8 (22), isobutyronitrile: 8 (22), propionitrile: 6 (14), malonitrile: 3 (8), adiponitrile: 4 (18), succinonitrile: 6 (20). All are ceiling values (15 min) in ppm (mg/m^3); acetone cyanohydrin: 1 (4); glycolonitrile: 2 (5), tetramethyl succinonitrile: 1 (6). When present as mixtures or with other sources of cyanide, exposures to be considered additive and environmental limit to be calculated	Acetonitrile: 40 ppm (70 mg/m^3), 8-hr TWA; tetramethyl succinonitrile: 0.5 ppm (3 mg/m^3), 8-hr TWA (skin)
53) Octane*	Criteria document (Alkanes)	75 ppm (350 mg/m^3) TWA	500 ppm (2,350 mg/m^3), 8-hr TWA

Chemical	Document Type	NIOSH Recommendation (REL)	OSHA Standard (PEL)
54) Organotins	Criteria document	0.1 mg tin/m^3 TWA	0.1 mg tin/m^3, 8-hr TWA
55) Pentane*	Criteria document (Alkanes)	120 ppm (350 mg/m^3) TWA	1,000 ppm (2,950 mg/m^3), 8-hr TWA
56) 2-pentanone* (Methyl n-propyl ketone)	Criteria document (Ketones)	150 ppm (530 mg/m^3) TWA	200 ppm (700 mg/m^3), 8-hr TWA
57) Pesticides, generic*	Criteria document	Specific substance recommendations only	
58) Polychlorinated biphenyls*	Criteria document	1 ug/m^3 TWA	42% chlorine: 1 mg/m^3, 8-hr TWA; 54% chlorine: 0.5 mg/m^3, 8-hr TWA
59) Refined petroleum solvents*	Criteria document	Kerosene 100 mg/m^3 TWA; all other solvents 350 mg/m^3 TWA; 1,800 mg/m^3 ceiling (15 min)	2,900 mg/m^3 (500 ppm), 8-hr TWA, (Stoddard solvent)
60) Styrene*	Criteria document	50 ppm (213 mg/m^3) TWA; 100 ppm (426 mg/m^3) ceiling	100 ppm, 8-hr TWA; 200 ppm acceptable ceiling; 600 ppm maximum ceiling (5 min in 3 hrs)
61) 1,1,2,2-Tetrachloroethane*	CIB #27	Reduce exposure to lowest feasible level based on potential as a carcinogen	5 ppm (35 mg/m^3), 8-hr TWA
62) Tetrachloroethylene* (perchloroethylene)	CIB #20	Reduce exposure to lowest feasible levels based on potential as a carcinogen	100 ppm, 8-hr TWA; 200 ppm acceptable maximum ceiling; 300 ppm maximum ceiling (5 min in 3 hr)
63) Toluene*	Criteria document	100 ppm (375 mg/m^3), 8-hr TWA; 200 ppm (750 mg/m^3) ceiling (10 min)	200 ppm, 8-hr TWA; 300 ppm acceptable ceiling; 500 ppm maximum ceiling (10 min)

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Chemical	Document Type	NIOSH Recommendation (REL)	OSHA Standard (PEL)
64) 1,1,2-Trichloroethane*	CIB #27	Reduce exposure to lowest feasible level	10 ppm (45 mg/m^3), 8-hr TWA (skin)
65) Trichloroethylene*	Special hazard review	25 ppm TWA	100 ppm, 8-hr TWA; 200 ppm acceptable ceiling; 300 ppm maximal ceiling (5 min in 2 hr)
66) Vanadium	Criteria document	Vanadium compounds: 0.05 mg/m^3 ceiling (15 min) metallic vanadium and vanadium carbide: 1 mg/m^3 TWA	Vanadium pentoxide (dust): 0.5 mg/m^3 ceiling; (fume): 0.1 mg/m^3 ceiling; ferrovanadium: 1 mg/m^3, 8-hr TWA
67) Vinyl bromide*	CIB #28	Lowest reliably detectable level based on potential as a carcinogen	None
68) Vinyl halides Vinyl chloride Vinylidene chloride Vinyl bromide Vinyl fluoride Vinylidene fluoride	CIB #28	Controlled as specified for vinyl chloride in 29 CFR 1910.1017 with eventual goal of zero exposure	None except for vinyl chloride: 1 ppm, 8-hr TWA; 5 ppm ceiling (15 min)
69) Xylene	Criteria document	100 ppm (434 mg/m^3) TWA; 200 ppm (868 mg/m^3) ceiling (10 min)	100 ppm (435 mg/m^3), 8-hr TWA
70) Niax Catalyst ESN	Joint NIOSH/OSHA CIB	Minimize occupational exposures to Niax Catalyst ESN and its components, dimethylaminopropionitrile and bis [2-demethylamino)ethyl] ether	

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Table 2. Ten Leading Work-Related Diseases and Injuries

1. Occupational lung diseases
2. Musculoskeletal injuries
3. Occupational cancers
4. Severe occupational traumatic injuries
5. Cardiovascular diseases
6. Disorders of reproduction
7. Neurotoxic disorders
8. Noise-induced loss of hearing
9. Dermatologic conditions
10. Psychologic disorders

Mr. VOLKMER. Thank you very much, Dr. Baker.
Mr. Tyson.

STATEMENT OF PATRICK R. TYSON, ACTING ASSISTANT SECRETARY OF LABOR FOR OCCUPATIONAL SAFETY AND HEALTH, U.S. DEPARTMENT OF LABOR

Mr. TYSON. Thank you, Mr. Chairman.

I'm going to read a summary of my prepared statement.

With me today is Dr. Edward Baker, seated behind me. He is the Director of Health Standards for OSHA.

OSHA regulates many substances which are known to be neurotoxic. These regulations are found in subpart Z of OSHA's general industry standards, and they are tables Z1, Z2, and Z3. These tables establish permissible exposure limits for the chemicals and substances limited that are listed therein. Other substances in OSHA's comprehensive health standards are also regulated in part on the basis of their neurotoxicity. For the most part, the exposure levels in the Z tables were established to prevent potentially adverse health effects other than neurotoxicity. This is the case because exposure to neurotoxic substances at levels that are below the threshold for the induction of neurotoxic effects are still capable of causing other adverse health effects.

This subcommittee has expressed particular interest in the recommendations by NIOSH on current permissible exposure levels in some of these standards. In the fall of 1983 OSHA asked NIOSH to review a list of chemical substances on which OSHA had taken some kind of preliminary regulatory action, such as publishing a

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request for information or an Advanced Notice of Proposed Rulemaking in the Federal Register, but for which the agency had not continued the rulemaking process.

The purpose of the NIOSH review was to identify the substances for which new data might indicate a need for regulation beyond that in the current OSHA standard. In October 1984 NIOSH recommended that OSHA proceed with rulemaking on 51 of the substances reviewed.

Consequently, OSHA has included these 51 substances in its submission to the Office of Management and Budget for the Federal Government's regulatory program for the period April 1, 1985 to March 31, 1986. OSHA's Regulatory Review Committee is examining the NIOSH regulations—excuse me, recommendations—to determine possible regulatory actions and alternatives.

In response to the subcommittee's question with respect to the stage of the regulatory process and the cost-effectiveness of OSHA's approach, it's far too early in the process to determine whether or not—to determine the cost-effectiveness of adopting NIOSH's recommendations. It needs to be pointed out that OSHA never balances relative costs and benefits in its rulemaking on health hazards. The Occupational Safety and Health Act of 1970 requires that standards controlling toxic substances or harmful physical agents attain the highest degree of health and safety protection for employees to the extent feasible. The act also requires that before a standard can be promulgated there must be a demonstration of significant risk. This principle was enunciated by the Supreme Court in a decision issued in July 1980 involving OSHA's standard for workplace exposure to benzene. In addition, OSHA must show that the standard in question will actually reduce that risk.

Along with the scientific data to justify the standard, OSHA must also gather data to show that the regulation is economically and technologically feasible for the industry as a whole. This requirement stems from the OSH Act as interpreted by several Federal appellate courts, starting with the case involving the Agency's asbestos standard back in 1971. Finally, Executive Order 12291 and the Regulatory Flexibility Act of 1980 require OSHA to carefully consider and systematically consider the economic consequences of all rulemaking. Thus, OSHA assesses the cost-effectiveness of alternative means for achieving an already-determined level of protection.

We have already begun work, preliminary work, on two of the substances for which NIOSH has recommended rulemaking. One is—I won't go through the scientific name; we call it MOCA or MBOCA—which EPA has under consideration, we understand, for a referral to OSHA under the Toxic Substances Control Act. The other is 1-3-butadiene. OSHA is also anticipating referral of this substance by EPA under the same TSCA authority.

Because OSHA's new regulations for toxic chemicals for the most part are more protective than would be necessary to guard solely against neurological effects, it might be useful to summarize briefly what the agency does in general to address hazards in the chemical industry.

As I have noted, we have issued a number of health standards which include permissible exposure limits or maximum allowable

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concentrations for approximately 400 toxic substances and materials, and comprehensive standards which go well beyond just a PEL for an additional 22 toxic substances. There are also OSHA standards to establish regulatory—excuse me—respiratory protection requirements and address the use of personal protective equipment.

For the thousands of chemicals in use in workplaces today, OSHA has promulgated a generic Hazard Communications Standard which I will discuss in the next panel, immediately following this one. OSHA enforces these standards by maintaining a high inspection presence in the chemical manufacturing industry. We inspected one out of every five chemical plants in this country last year. We visit 1 in every 40 of all establishments in this country in any given year.

In addition to the standard-setting and enforcement activity, the OSH Act has a variety of assistance programs to address workplace hazards. Among these is OSHA's onsite consultation program, which is conducted by the States with Federal funding. And under this program an employer may request a free visit to go through the workplace to determine what hazards may exist in that workplace, and the consultant will recommend corrective action. We did some 35,000 of those visits last year, mostly covering smaller workplaces.

We also provide educational grants to unions and trade associations to help them develop competence in addressing these kinds of hazards from a training standpoint. The grant—or excuse me, the program—that the painters have that Dr. Baker mentioned earlier, was in major part funded through an OSHA New Directions training grant. We've given the painters $1.3 million to work on these types of problems.

We also have voluntary protection programs which offer other incentives to a select number of employers who are outstanding in the area of safety and health protection. We'd like--we need to recognize them as well.

Those are my prepared remarks. I'd be happy to answer any questions when the committee wishes.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Tyson follows:]

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STATEMENT OF PATRICK R. TYSON, ACTING ASSISTANT SECRETARY OF LABOR FOR OCCUPATIONAL SAFETY AND HEALTH

Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to discuss the health effects of neurotoxins and efforts by the Occupational Safety and Health Administration (OSHA) to protect employees from the adverse effects of exposure to these substances. We will also discuss the agency's surveillance of permissible exposure limits and the coverage provided by OSHA's Hazard Communication Standard.

Neurotoxins

Some neurotoxic substances are known to cause acute effects on the central nervous system as a result of high levels of exposure, while othere are known to cause chronic effects on the peripheral nervous sytem. There are chemicals, however, that are capable of reactions with both the central nervous system and the peripheral nerves. These reactions are highly site-specific and depend upon the chemical structure of the toxic substance. Acute effects on the central nervous system, such as narcosis or staggering, may occur when a substance reaches a concentration high enough to pass the blood-brain barrier where it reacts and causes swelling and/or inflammation of the brain. This type of response can occur

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as a result of high level occupational exposure to substances such as benzene or other solvents and has been observed in LD_{50} studies of experimental animals. (LD_{50} is the lethal dosage of a substance which is expected to cause the death of 50 percent of an entire group of animals.)

OSHA regulates many substances which are known to be neurotoxic. These regulations are found in Subpart Z (Toxic and Hazardous Substances) of OSHA's General Industry Standards. Tables Z-1, Z-2, and Z-3 of Subpart Z establish permissible exposure limits for the chemicals and substances listed. Other substances in OSHA's comprehensive health standards such as ethylene oxide, lead, and acrylonitrile also are regulated in part on the basis of their neurotoxicity. For the most part, the exposure limits in the Z Tables were established to prevent potentially adverse health effects other than neurotoxicity. This is the case because exposure to neurotoxic substances at levels that are below the threshold for the induction of neurotoxic effects are still capable of causing other adverse health effects.

NIOSH Standards Recommendations

In the fall of 1983, OSHA asked the National Institute for Occupational Safety and Health (NIOSH) to review a list of chemical substances for which OSHA had taken some kind of preliminary regulatory action, such as publishing a request for information or an Advance Notice of Proposed Rulemaking

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(ANPR) in the Federal Register, but for which the agency had not continued the rulemaking process. The purpose of the NIOSH review was to identify the substances for which new data might indicate a need for regulation beyond the current OSHA standard. In October 1984, NIOSH recommended that OSHA proceed with rulemaking on fifty-one of the substances reviewed.

Consequently, OSHA included these fifty-one substances in its submission to the Office of Management and Budget for the Federal Government's Regulatory program for the period, April 1, 1985 to March 31, 1986. OSHA's Regulatory Review Committee is examining the NIOSH recommendations to determine possible regulatory actions and alternatives.

In response to the Subcommittee's question in its letter of invitation, let me say that at this stage in the regulatory process, it is too early to determine the cost-effectiveness of adopting NIOSH's recommendations. It should be noted that OSHA never balances relative costs and benefits in its rulemaking on health hazards. The Occupational Safety and Health Act of 1970 (the OSH Act) requires that standards controlling toxic substances or harmful physical agents attain the highest degree of health and safety protection for employees, to the extent feasible. The Act also requires that before a standard can be promulgated, there must be a demonstration of significant risk. This principle was enunciated by the

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Supreme Court in a decision issued in July 1980 involving OSHA's standard for workplace exposure to benzene (Industrial Union Department, AFL-CIO v. API). The agency must further show that the standard will actually reduce the risk. Along with scientific data to justify the standard, OSHA must also gather data to show that the regulation is economically and technologically feasible for the industry. This requirement stems from the OSH Act as interpreted by several Federal Appellate courts, starting with a case involving the Agency's asbestos standard (IUD v. Hodgson). Finally, Executive Order 12291 and the Regulatory Flexibility Act of 1980 require OSHA to consider carefully and systematically the economic consequences of all rulemaking. Thus OSHA assesses the cost-effectiveness of alternative means of achieving an already determined level of protection.

We already had begun preliminary work on two of the substances recommended for rulemaking by NIOSH. One is 4,4 methylene bis (2-chloroaniline), also referred to as MOCA and MBOCA, which the Environmental Protection Agency (EPA), we understand, has under consideration for referral to OSHA under the Toxic Substances Control Act (TSCA). The other is 1,3-butadiene. OSHA is also anticipating referral of this substance by EPA under the same authority.

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On November 25, 1983, OSHA published a final rule entitled "Hazard Communication" (29 CFR 1910.1200). The promulgation of this standard was the culmination of nearly ten years of rulemaking activity on the controversial and complex issue of giving employees the "right to know" the identities and hazards of substances they are exposed to during the course of their employment. OSHA believes, and the rulemaking record supports, that when employers have information about the chemicals in their workplaces, they are better able to devise and implement proper protective measures for their exposed employees. When employees have such information, they are better able to support and participate in such programs, as well as take steps to protect themselves. Thus this rule should result in a reduction in the occurrence of illnesses and injuries from chemical sources among those employees covered by the rule.

The Hazard Communication Standard represents a unique approach to regulating occupational safety and health. The agency's rulemaking experience to date has shown that the process OSHA must follow to promulgate a standard is a lengthy and complicated one, and it can be expected that few substance-specific rules will be adopted relative to the number of chemicals in the workplace. The agency has determined that requiring information on hazards and associated protective measures, and additionally requiring that this information

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be transmitted to employees and downstream employers, will provide protection for workers exposed to the many thousands of chemicals for which there is no substance-specific standard at this time. This generic approach to rulemaking will result in 14 million workers, exposed to as many as 575,000 chemical products in the manufacturing industrial sector, being given information regarding the identities, hazardous properties, and precautions for safe handling and use of these products.

The basic premise of the rule is that employers who produce or distribute hazardous chemicals are in the best position to evaluate those hazards, and generate the appropriate information. The standard incorporates a downstream flow of information. Chemical manufacturers and importers are required to evaluate the hazards of the chemicals they produce or import. Chemical manufacturers, importers, and distributors are then required to ensure that containers of hazardous chemicals are labeled with appropriate information when they leave the suppliers' workplaces and that material safety data sheets are provided to manufacturers who purchase the chemicals. Any employer in any industry will thus be receiving containers that are labeled as to the identity of the material, along with appropriate hazard warnings and the name and address of the supplier or responsible party. Employers who are manufacturers will also be receiving further detailed information through the transmittal of material

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safety data sheets regarding the physical and chemical characteristics of the material, its hazardous effects, and control measures. In addition to these written materials, all employers in the manufacturing sector are required to prepare and implement a hazard communication program and to train employees regarding the chemicals they are exposed to and the means to protect themselves. This comprehensive approach to communicating hazards should ensure that employees both have and understand the information they need regarding the substances in their work areas.

All employees will have access to information on the labels on containers in their workplaces. OSHA chose to have additional coverage of workers in the manufacturing sector because, according to the Bureau of Labor Statistics, more than half the reported illnesses and injuries from chemical sources occur in manufacturing, although this sector only accounts for about thirty percent of total employment. Since the underlying purpose of the rule is to reduce the incidence of chemical source illnesses and injuries, it appeared that the standard should focus on the sector where they were occurring with the greatest frequency.

Challenges to the Standard were filed in a number of appeals courts following publication of the rule. All of these cases were consolidated into one action in the Third Circuit of the U.S. Court of Appeals. The Court issued its

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decision in this matter on May 24, 1985. The requirements of the rule were substantially upheld, but the Court did remand three issues to OSHA for reconsideration. One involves the scope of employees covered. The Court had directed OSHA to expand coverage to employees in non-manufacturing industries unless it finds that such expansion is not feasible. Responding to this remand will require re-opening of the rulemaking on this project. OSHA plans to publish an Advance Notice of Proposed Rulemaking on expansion of the scope some time in the near future, to help the agency collect information on the current extent of hazard communication programs in industries other than manufacturing and the feasibility of extending to those sectors the provisions as currently written.

The Court has also ordered OSHA to reconsider the definition of "trade secret." OSHA has been directed to narrow the definition to ensure that it is not broader than applicable State laws and does not permit chemical identity information to be considered a trade secret if it is readily discoverable through reverse engineering. In addition, the Court has directed OSHA to extend access to trade secret information to employees and collective bargaining agents who have a need to know such data. (The current rule only extends such access to health professionals.) OSHA plans to address both of these issues in an interim final rule, to be published prior to the initial compliance date for the standard--November 25, 1985.

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I think it is fair to say that there has been more public interest in this standard than in any other ever promulgated by OSHA. During the two-year phase-in period for compliance that will soon be completed, OSHA has had numerous inquiries from employers and employees concerning the requirements of the standard and has devoted considerable staff resources to assisting the affected employers to come into compliance. The agency is currently in the process of designing a special emphasis program to be implemented between November 25, 1985, and the second compliance date, May 25, 1986, to ensure that suppliers are providing the required information to their downstream customers. OSHA has also conducted intensive training for its compliance staff to prepare them to enforce this ground-breaking rule.

With respect to the subject of this hearing, neurotoxins, it can be expected that the Hazard Communication Standard will result in significant additional information being available to employees and employers regarding neurotoxic effects. As stated previously, it is OSHA's contention, supported by the evidence in the record, that this type of information can and will result in a reduction in the occurrence of such health effects, by ensuring that appropriate protective measures are identified and implemented.

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Although the standard as currently drawn focuses on the manufacturing sector, information on labels will be available throughout industry so that employees in non-manufacturing will benefit as well. Since material safety data sheets have to be generated in manufacturing, it is expected that they too will become more readily available in sectors other than manufacturing and that employees will benefit from this as well.

Moreover, the Access to Employee Exposure and Medical Records regulation, which went into effect in August 1980, covers all workers exposed to hazardous chemicals--employees outside the manufacturing sector as well as employees in that sector. Under the Access regulation, all of these employees already have access to records of their employers giving information about chemical hazards. Any new informational materials generated by the Hazard Communication Standard will also be available to employees outside the manufacturing sector under the Access regulation. This regulation is considered to be part of the comprehensive right-to-know package developed by OSHA and is complementary to the Hazard Communication Standard provisions regarding transmittal of information.

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Workplace Monitoring

Employee exposure to harmful toxic and physical agents is routinely assessed during OSHA inspections. Consequently, worker exposure to neurotoxins is evaluated whenever a potential for overexposure is recognized in the workplace.

OSHA compliance officers use a variety of techniques in conducting inspections. Among other things, they interview employees, review employer safety and health programs, and analyze existing medical and exposure monitoring results. When there is a possibility of excessive airborne exposure to chemicals, air sampling is conducted.

When problems are found, employers are required to implement all feasible engineering and administrative controls to reduce contaminants to safe levels. Respiratory protection and medical surveillance programs, which measure biological indices under various standards such as lead and arsenic, are generally an integral part of employers' protection programs. In many cases respiratory protection is permitted only while other permanent control measures are being installed.

The Hazard Communication Standard has not yet gone into effect. Program activity will be carefully monitored once it is implemented. Under development is a special emphasis program for enforcement of the standard. OSHA compliance officers will make a special effort to ensure that employers comply with provisions of the standard as they go into effect.

That completes my prepared statement. I will be happy to answer any questions you may have.

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Mr. VOLKMER. Thank you, Mr. Tyson.

We'll now hear—I don't know which one wants to go first or who's going to be the spokesman. Mr. Gough.

STATEMENT OF MICHAEL GOUGH, PROJECT DIRECTOR, HEALTH PROGRAM, OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS

Mr. GOUGH. Yes. Thank you, Mr. Chairman.

Members of the subcommittee, I am Michael Gough. I am accompanied by my colleague, Karl Kronebusch.

We will summarize our written testimony.

We will discuss some conclusions from consideration of personal protective equipment and the hierarchy of controls that were published in the OTA report, "Preventing Injury and Illness"—excuse me, "Preventing Illness and Injury in the Workplace," in April of this year.

Although our conclusions are general and not limited to protecting against neurotoxins, they illuminate the difficulties of using personal protective equipment to protect against substances that can be inhaled, ingested, or that pass through the skin.

Our written testimony describes some of the limitations of and knowledge of the actual effectiveness of personal protective equipment and some of the problems encountered in the use of those devices, especially respirators.

Currently, most employers and workers rely on results obtained from very limited research in laboratory settings to choose appropriate respirators. They also rely on NIOSH to test and certify respirators.

There are many complaints about this NIOSH Program. It is slow and cumbersome, and its standards, developed over the last 50 years, are accused of retarding development in new designs.

There are also limitations in quality control in the respirator industry. For instance, the first test that NIOSH applies to its respirator is called the shake test. In that test a NIOSH employee takes a respirator out of its shipping box, shakes it vigorously, and if some of the pieces fall off, the respirator is sent back to the factory having failed that first test.

The respirators that pass that test then go through a series of efficiency tests. While the tests are generally accepted as appropriate, they tend to maximize the apparent effectiveness of the devices.

Let's consider a worker's day. He or she walks around or rides from place to place, reaches and lifts, bends and stretches, gestures and converses, eats and drinks. Each of those actions may affect the fit of a respirator, and some of them require its removal.

Even if the respirator provided protection equivalent to that measured in the laboratory at the start of the workday, it is unlikely that those conditions would prevail at the end of a shift.

Unfortunately, there are only a few reports that describe field testing of respirators. The major conclusions reached from these field studies are obvious. Respirators do not protect unless they are worn, and the degree to which they afford protection depends on how well they fit and how well they are maintained.

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According to OSHA inspection data, many workplaces fail to insure that respirators are used and neglect the maintenance necessary to assure that the respirators work properly.

The protection realized by workers in several field studies was substantially less than that predicted from laboratory tests. Far more positive data are reported from workplaces with tightly supervised programs in which workers wore their masks for relatively short periods of time.

But good respirator programs are largely limited to very large workplaces where time and effort are expended on them. All of this information warns against reliance on respirators to protect against neurotoxins.

There is even less information available about the protection afforded by protective clothing. Gloves have been the most studied, and these tests show that many chemicals penetrate so-called chemical-resistant glove materials quite quickly—in minutes or seconds.

Before Karl discusses the hierarchy of controls, I will mention results from a different OTA report that was published in 1983. As you know, the Toxic Substances Control Act requires that companies notify the Environmental Protection Agency 90 days before they begin the manufacture of a new chemical. As a part of this notification, the company has to submit any toxicological data that it has about the chemical.

OTA examined 740 premanufacture notices which were received in the first 2 years of the program. None contained information about neurotoxicity.

STATEMENT OF KARL KRONEBUSCH, ANALYST, HEALTH PROGRAM, OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS

Mr. KRONEBUSCH. Personal protective equipment is not the only nor the preferred method to protect against health hazards. Controls can be introduced at several points to interrupt the transmission of hazardous agents to workers. Put simply, the principle of the hierarchy of controls is to control the hazard as close to the source as possible by using engineering controls and substitution, rather than relying on personal protective equipment.

The hierarchy of controls is widely supported in the professional community and now has regulatory force under OSHA's standards. The first and most important reason for this approach is that many types of existing personal protective equipment do not provide reliable, consistent, or adequate levels of protection.

As Mike indicated, research conducted on the real world effectiveness of such equipment shows that the protection provided by these devices is highly variable and often substantially lower than that predicted from laboratory measurements. These shortcomings frequently make personal protective equipment inadequate for worker protection.

Engineering controls include substitution of less toxic materials, enclosure of hazardous operations, and increased ventilation. These controls are inherently more reliable, provide more effective protection than personal protective equipment, and are more likely to result in successful hazard control.

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There are other advantages to engineering controls. Personal protective equipment requires constant supervision and monitoring, measurement of its actual effectiveness is difficult, and the use of this equipment is often physically burdensome for employees. Furthermore, placing emphasis on the development of engineering controls can spur the advance of technology.

Notwithstanding the advantages of engineering controls, there are some drawbacks. First, although they are less subject to human error and inherently more reliable than personal protective equipment, engineering controls can fail.

Second, they are not always feasible and they can be more costly than personal protective equipment.

Since its creation in 1971, OSHA has required the use of engineering controls as the primary method to control exposures to toxic substances in the workplace. In February 1983, OSHA announced that it was conducting a review of its general policy toward the hierarchy of controls. Many individuals and organizations have responded to that announcement.

Most health professionals endorse primary reliance on engineering controls. For instance, the members of the OTA Advisory Panel convened for our assessment supported the hierarchy of controls.

In several specific regulatory proceedings over the last few years OSHA has sometimes favored continuation of the traditional policy and sometimes has proposed changes.

However, to turn away from the hierarchy of controls without careful verification of the levels of protection provided by personal protective devices is likely to increase exposures to health hazards. Although there is a role for personal protective equipment in protection against neurotoxins, it is clear that this equipment needs careful selection, testing, and maintenance to be effective.

Finally, worker protection from neurotoxins requires further Government and industry research to improve that equipment and engineering controls.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Gough and Mr. Kronebusch follows:]

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Testimony of Michael Gough, Project Director, and Karl Kronebusch, Analyst, Health Program, Office of Technology Assessment, U.S. Congress

I am Michael Gough and I am accompanied by Karl Kronebusch. We will discuss some conclusions from considering personal protective equipment and the hierarchy of controls in the Office of Technology Assessment (OTA) report, *Preventing Illness and Injury in the Workplace*. Although our conclusions are general, and not limited to protection against neurotoxins, they illuminate the difficulties of using personal protective equipment to protect against substances that can be inhaled, ingested, or that pass through the skin.

Effectiveness of Respirators and Protective Clothing

In our report, we concluded that the effectiveness of personal protective devices, especially under conditions of use in the workplace, has not been demonstrated. Instead, many devices have been tested only in laboratory situations that do not duplicate and may not even approximate workplace conditions. The overall impression is that test results tend to exaggerate the effectiveness of personal protective devices. Additionally, the few in-workplace evaluations reveal that continual maintenance and supervision, which are seldom provided, are necessary for acceptable performance.

The most common respirators are "dust masks". They employ fiber filters to prevent particles from being inhaled. The second general class of respirators are "gas masks," familiar to most veterans of the armed forces. They purify air contaminated with fumes and vapors by passing it through a chemical "sorbent." Less common are "air supply devices." "Dust masks" and the "gas masks" are negative-pressure respirators, relying on the wearer's breathing to pull "outside" air across the filter or sorbent. "Air supply devices" are positive pressure respirators which supply clean air to the wearer from a tank or from a hose that originates in an area of clean air.

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Our review of the literature on the effectiveness of personal protective equipment did not focus on neurotoxins, although one neurotoxin, lead, was the air contaminant examined in two relatively recent studies. The general conclusions of our review do, however, apply to neurotoxins. Moreover, many solvents may be neurotoxic. Because many solvents tend to "eat away" at the materials used to make respirators and protective clothing, they are likely to present special challenges for protecting worker health.

Workers exposed to neurotoxins as well as other toxic substances often depend on respirators to reduce their exposures. Adequate protection requires that at least 4 separate conditions be met:

1. the class of respirator selected by the employer must provide a sufficient reduction in the level of toxic exposure,
2. the particular model (brand, type) of respirator must "work" in general
3. the particular respirator used by the individual worker must fit that worker
4. the respirators must be adequately maintained and must be used.

The actual, real-world protection provided to workers is the result of all four conditions.

1. Class ratings for respirators. The traditional measure of the effectiveness of a respirator is called the "protection factor" (PF), which is the ratio between the concentration of an airborne contaminant outside the mask to the concentration found inside the mask. For instance, a PF of 10 means that the respirator purifies away 90 percent of the toxic substances in the air. Therefore if the concentration of the toxic substance is known, and it is known that reducing it 90 percent will protect workers' health, a respirator with a PF of 10 would be suitable.

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In practice, few employers can determine PFs directly. Instead they and workers rely on PF values assigned by the the Los Alamos Scientific Laboratory (LASL). That laboratory's studies are often regarded as thorough and definitive. Nevertheless, their importance does not appear to be based on their superiority to other studies. Rather, they appear to be the only studies available for many respirator types. In fact, before LASL began its studies in 1969, no one had conducted systematic laboratory tests of respirators. Furthermore, the first field studies of respirator effectiveness were not published until 1973 and few have been reported. Over 2 million workers who wear respirators rely on this limited research for assurance of protection.

2. NIOSH Certification of Respirators. NIOSH tests complete respirator systems consisting of the mask and any air-purifying filters, cartridges, and canisters or air supply apparatus. The agency certifies the respirator for specified uses (for instance, against a particular chemical) and if the manufacturer subsequently decides that he would like certification of the same respirator against another hazard, he has to submit the new use for NIOSH approval.

In large part, NIOSH's testing specifications (30 CFR Part 11) were developed, published, and revised by the Bureau of Mines from 1920 through 1970. Those somewhat dated specifications, adopted by NIOSH in the early 1970's, have been criticized by industry and government officials because they are believed to restrict innovation in respirator design and to be inappropriate for testing devices that will be used in the workplace. To date, however, opponents of the current regulation have been unsuccessful in getting a new version adopted.

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Increasing emphasis on workplace health has been accompanied by a greatly increased work load; in 53 years, the Bureau of Mines approved 340 devices, or about 6 each year. In 1981, NIOSH issued 99 new approvals. This large number of approvals does not show that innovative respirators have been introduced because each time an "old" design is cleared for a new use, it receives an additional approval.

In general, the resources of NIOSH are seen as being woefully inadequate to carry out all the desired activities in the area of respiratory protection research and development, testing, and certification. OTA staff heard many complaints about NIOSH's testing and certification program--primarily that it was slow and bureaucratic, restricted innovation, and depended on outdated criteria for an acceptable respirator.

While all those complaints evidently have some basis in fact, NIOSH is far from satisfied with all the companies in the respirator industry. For instance, the first test that NIOSH applies to a respirator when it arrives for testing, "the shake test," reflects that quality control is not always good. In that test, a NIOSH employee takes the respirator out of the box in which it arrives, shakes it vigorously, and if some piece or pieces falls off, the mask is sent back to the manufacturer.

3. Fitting of Respirators. Most tests of respirator effectiveness are conducted in laboratories and usually maximize the apparent effectiveness of the devices. For instance, most air-purifying (negative pressure) respirators depend on the user's inhalation to create a negative pressure inside the mask. In theory, the only source of air to equalize the pressure is air that passes through the air-purifying system (i.e., a filter or sorbent). The practical realization of the theory requires that the seal between the edges of the mask

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and the wearer's face be sufficiently tight to prevent contaminated air leaking in from the sides. Many factors may reduce the security of the seal -- changes in the tension of the headstraps that secure the mask, daily growth of facial hair or the presence of a beard, perspiration, head movements, and talking. Although laboratory tests attempt to make allowances for such factors, no test duplicates "field situations."

Two general methods are available to test whether the respirator is properly worn, and, indeed, if a particular respirator can protect an individual. Both methods have advantages and disadvantages. What must be stressed is that proper fitting is important to achieving protection and that proper fit is sometimes difficult to achieve.

6. Maintenance and use of Respirators. Although respirator program experts repeatedly point out the importance of equipment maintenance and supervision of use to achieve high protection factors, data from OSHA inspections reveals deficiencies in 40 to 70 percent of respiratory protection programs in inspections in which toxic overexposure was documented. Simply providing good respirators in a workplace is not enough.

Even when used, there is often little warning to a worker that his/her respirator has failed. For example, for a dust mask in a very dusty workplace, the first indication may be streaks of dust on the worker's face. Short of such drastic failures, tasting or feeling the dusty material on the mouth or nose may alert the worker to the absence of sufficient protection. On the other hand, a person's senses may become acclimated to the dust, rendering the worker unable to detect the mask's failure.

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It must be remembered that respirators must be used continuously if they are expected to provide protection. A respirator with a PF of 100 that is not worn for one minute per hour provides an PF of only about 40; if not worn for 6 minutes, the PF is only about 10. No one denies that respirators can be hot and uncomfortable, and that they can interfere with conversation and work. This is an important disadvantage of respirators and an important part of a respirator program is to remind workers to wear their respirators.

Respirator Performance

In the course of a day, a worker walks or rides or runs from place to place, reaches and lifts, bends and stretches, gestures and converses, eats and drinks. Each of those actions may affect the fit of a respirator, and some of them require its removal. Even if the respirator, at the start of the workday, provided protection equivalent to that measured in the laboratory, it is unlikely that those conditions would prevail at the end of a shift. There are only a few reports that describe field testing of respirators. The more sophisticated of these studies involve attaching one sampling device to the worker's clothing and one inside the respirator and measuring concentrations of airborne dusts, fumes, and vapors inside and outside the respirator. These measurements are then used to calculate the protective factors realized by the respirators.

NIOSH reported on the use of respirators in the abrasive blasting industry during 1971-73. The results were not encouraging; PFs ranged from 3,750 to less than 2. Lower PFs were associated with poor maintenance, poor training, poor fitting of respirators, and inadequate supervision of use. Although in many cases inappropriate respirators were used, low PFs (2 or less) were found in at least some cases with all types of respirators,

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pointing to problems of fit, maintenance, and use.

Similar findings of poor respiratory protection were also reported in NIOSH-contracted studies of paint-spraying operations and coal mining. When wearing of the mask was closely supervised, coal miners achieved PFs approaching those measured in the laboratory, at least for relatively short periods of time under conditions of close observation and continuous use. However, those high levels of protection were seldom reached under conditions of normal use. In the tests of effectiveness against coal dust, some PFs were less than 1.0, which means that the concentration inside the mask was higher than the concentration outside. That was brought about by dust collecting in respirators while hanging around miners' necks.

The major conclusions reached from these field studies are that respirators do not afford protection unless they are worn and that the degree to which they afford protection depends on how well they fit and how well they are maintained. Overall, then, the protection factors realized by workers in the studies of coal miners and cadmium workers were about one-third those predicted in the laboratory. Moreover, a number of workers in each study were receiving little protection or no protection at all.

Tightly supervised respirator programs in which workers wore their masks for 30 minutes to 2 hours found very high PFs--from 40 to greater than 27,000. One reason offered the high PFs was the use of a new model of respirator with a comfortable silicon facepiece. In addition, these results were found in workplaces with good respirator programs and "adequate fit testing."

Tests of Gloves Against Chemical Hazards

There is even less information available about the protection provided

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by protective clothing. Protective gloves have been studied, and manufacturers, in their literature, rate various types of gloves as providing "excellent, good, fair, or poor" protection against workplace chemicals. There seems to be little reason for the general assignments of resistance to chemicals, because many chemicals penetrate "chemical-resistant" glove materials quite quickly.

Some workplace solvents, for instance halogenated ethanes (dichloroethanes and trichloroethanes) and polychlorinated biphenyls (PCBs), have presented special problems because they penetrate most gloves in minutes or seconds. For example, in one study of commonly used glove materials, the tested substances generally broke through in less than five minutes. A relatively new material did provide excellent resistance to the halogenated ethanes, however, and better resistance to PCBs than any other tested material. Yet the new gloves may not be used widely because of the high cost -- 10 times as much as any other glove.

In any case, relying on protective clothing to protect against dermal exposure to neurotoxins requires testing of the clothing material for resistance to the particular toxic substances. Then, as with respirators, the clothing must be used and maintained.

Hierarchy of Controls

Personal protective equipment is not the only, nor the preferred method to protect against health hazards. Such hazards are controlled by interrupting the transmission of hazardous agents to workers. Controls can be introduced at several points: the source of the hazard, the workers' location, and the workplace atmosphere. For health hazards, control at the source can include substitution of less toxic agents or substances, as well as

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process and engineering changes to reduce emissions of the hazardous agents or substances. Control of transmission of the agent can be accomplished by ventilation, isolation, dilution, or enclosure. Control at the worker can include personal protective equipment, work practices, and administrative procedures.

Put simply, the principle of the hierarchy of controls is to control the hazard as close to the source as possible. The hierarchy of controls describes the order that either should be followed or must be followed when choosing among options for controlling health and safety hazards. This ranking is often expressed as: engineering controls, work practice controls, and personal protective equipment. Administrative controls, such as worker rotation, are also oftentimes included and generally constitute the "third" line of defense, falling after engineering controls and work practice controls and ahead of protective equipment.

The hierarchy of controls is widely supported in the professional community. Every current industrial hygiene textbook endorses the idea of such a hierarchy and lists engineering controls as the first priority and personal protective equipment as a last resort. Elimination of contaminants in the workplace atmosphere by substitution of materials, enclosure of operations that generate fumes and vapors, dust suppression methods, or dilution of the contaminants by ventilation are all preferred over reliance on respirators. The hierarchy of controls is also found in the "consensus" standards written by committees meeting under the auspices of the American National Standards Institute (ANSI), as well as in guidelines provided by the American Conference of Governmental Industrial Hygienists.

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The conclusions and practices of the professional community and the consensus standards organizations now have regulatory force because the hierarchy of controls approach was adopted by OSHA in its "startup" standards adopted in 1971 and in subsequent substance-specific rulemaking proceedings. Personal protective equipment, such as gas masks and respirators, are to be used against airborne contaminants only during the time period necessary to install feasible engineering and work practice controls, when engineering and work practice controls are not feasible, when engineering and work practice controls are not sufficient to achieve compliance with the permissible limits, and in emergencies.

Advantages of the Hierarchy of Controls. The first and most important reason for the hierarchy of controls approach is that many types of existing personal protective equipment do not provide reliable, consistent and adequate levels of protection. Indeed, research conducted on the real-world or workplace, as opposed to laboratory, effectiveness of such equipment shows that the protection provided by these devices is unequal, highly variable, and often substantially lower than that predicted from laboratory measurements. These shortcomings often make personal protective equipment inadequate for worker protection.

Engineering controls are inherently more reliable, provide more effective protection than personal protective equipment, and are more likely to result in successful hazard control. Once installed and adequately maintained, engineering controls provide reliable and consistent performance, and, if designed correctly, adequate levels of protection. Because they do not depend on a "good fit" with workers, they provide the same protection to all, and monitoring devices can measure the protection afforded. Separated

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from contact with the worker, engineering controls do not create additional health or safety problems. Moreover, these controls, especially those at the source of a hazard, can simultaneously control several exposure routes, e.g. respiratory and dermal exposure, while protective equipment is generally limited to protecting against only one exposure route.

In addition, OTA has identified five other advantages of engineering controls. First, the constant supervision of personal protective equipment programs, such as respirator programs, is beyond the capability of many employers. A leading consultant in the field has summarized his experience:

> ...having reviewed the respirator programs of hundreds of private companies, I can state that I have not, with the exception of the nation's very largest corporations, ever observed a proper and adequate use of respirators in the occupational setting.

Second, it is generally impossible to make periodic measurements of the effectiveness of personal protective equipment while it is being used and it is very difficult to monitor each individual employee as he/she cleans, dons, and uses his/her equipment. Third, in a hierarchical approach, with control achieved close to the source of the hazard, there is room for backup or supplemental controls. For example, if the primary control involves the use of process containment, then this control can be supplemented by having personal protective equipment available for emergency use. If the primary control is protective equipment, the opportunity to provide for supplemental control is eliminated.

Fourth, primary reliance on engineering controls can spur the advance of technology. New control technology can be, and has been, accompanied by other changes in plant and equipment that improve productivity, as well as protecting worker health and safety. For example, if OSHA had permitted the

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use of dust masks to comply with the cotton dust standard, the installation of new technology in the cotton textile industry would probably not have taken place as rapidly as it did. Modernized equipment has both dramatically improved productivity and lowered worker exposures to cotton dust.

Finally, personal protective equipment is burdensome on employees. It is usually uncomfortable, decreases mobility, and the weight of many types of personal protective equipment increases employees' physical work loads. Negative-pressure respirators, in addition to their discomfort, also significantly increase the effort needed for breathing. This can create special difficulties for workers who already suffer from lung impairments.

Problems with Engineering Controls. Notwithstanding the advantages of engineering controls over personal protective equipment, there are some drawbacks. First, although they are less subject to human error and inherently more reliable, engineering controls can fail. No matter how well designed, a ventilation system will fail to remove an airborne contaminant if the filters are not regularly changed or if the fan stops. Although these failures can be kept to a minimum with adequate maintenance, respirators must be available for use in such emergencies.

Even substitution does not eliminate the possibility of a failure in hazard control. For example, carbon tetrachloride, which had been used as a substitute for petroleum naphtha, is now widely recognized as toxic itself. Some of the substitutes for carbon tetrachloride (tricholoroethylene, perchloroethylene) are now suspected of having various previously unrecognized toxic effects.

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Second, there are a number of situations for which feasible control methods have not yet been fully developed. In these situations, the best that can be done is to require the use of personal protective equipment while attempting to develop feasible engineering controls. In addition, such equipment will always be needed when engineering controls are insufficient to reduce exposures to permissible levels and during the interim period while engineering controls are being designed and implemented.

These situations are widely recognized and are provided for in OSHA's hierarchy of controls. There are, and will be, however, disputes about what kinds of controls are "technologically feasible" in any given situation. This is particularly true when OSHA issues a regulation that "forces" technology, either by speeding development of control techniques or by facilitating dissemination of existing techniques.

Cost is the principal objection to requiring engineering controls. Although a well-designed and well-conducted respirator program can be expensive, such programs are in many cases cheaper than engineering controls and certainly capital costs are lower. Some employers and economists have suggested that employers should be allowed the flexibility to choose among the available control methods, rather than being required first to install feasible engineering controls.

Many employers believe that the use of personal protective equipment can provide adequate employee protection at reduced cost. This argument is used with regard to both full eight-hour exposures, as well as for brief and intermittent exposures. These industry representatives argue that if the degree of protection offered by the equipment is equivalent to that provided by engineering controls, it is would be sensible to choose the least costly

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means. Unfortunately, as already noted, many kinds of protective equipment have not been demonstrated to be effective in actual workplace conditions.

OSHA's Policy toward the Hierarchy of Controls. Since its creation in 1971, OSHA has required the use of engineering controls. In February 1983, OSHA published an Advance Notice of Proposed Rulemaking announcing that it was conducting a review of the hierarchy of controls and requesting information and comments from the public. In light of OSHA's reconsideration, the members of the OTA advisory panel for our assessment, *Preventing Illness and Injury in the Workplace*, asked to be recorded as endorsing the hierarchy of controls. To turn away from the hierarchy of controls without careful verification of the levels of protection afforded by personal protective devices is likely to increase exposures to health hazards.

During that last few years, OSHA has sometimes favored continuation of the traditional policy and sometimes proposed changes. In reconsideration of the cotton dust standard, OSHA decided to continue to require engineering controls. However, in a proposal concerning a new standard for ethylene dibromide (EDB), OSHA proposed for the first time to allow use of respirators as the primary means of control in cases of intermittent exposure. In its 1984 proposal for a new asbestos standard, the Agency proposed that employers be allowed to use respirators on a continuous basis as the primary means to comply with a new, reduced exposure limit.

In its final rule for ethylene oxide exposures, OSHA concluded that for some situations, engineering controls to meet the eight-hour time-weighted average for ethylene oxide were not feasible and, for the first time in any health standard, specifically lists those operations in the text of the regulation. For those situations, employers are allowed to issue respirators

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as the primary means of control. The issue of using respirators for short-term exposures became moot because OSHA did not issue any short-term exposure limit for ethylene oxide.

OSHA's re-evaluation of its long-standing policy favoring engineering controls for airborne contaminants may indicate a shift in the agency's approach to the hierarchy of controls. That policy has led to improvements in the health of U.S. workers and has spurred, at least to some extent, the development of control technologies. Policy changes that allow greater use of personal protective equipment may endanger the health and well-being of many American workers and reduce the regulatory imperative to develop new and better production and control technologies.

Protection against neurotoxins, which can enter the body through inhalation, ingestion, or the skin, will be best accomplished by engineering controls. As attention shifts to these substances, it can be expected that the often-repeated arguments of the costs of engineering controls not being justified will be heard again. Although there is a role for personal protective equipment in protection against neurotoxins, it is clear that this equipment needs careful selection, testing, and maintenance to be effective. Both government and industry spending on research to improve that equipment and engineering controls are necessary to protect workers from neurotoxins.

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Mr. VOLKMER. Thank you.

I'll now recognize the gentleman from California for any questions he may have.

Mr. PACKARD. Thank you, Mr. Chairman.

In your testimony, Mr. Gough, you indicated that the—I think, in fact, maybe Mr. Kronebusch was the one that just stated it—the preference of engineering controls over personal protective equipment. Is it an either/or or is there a combined process that's been implemented or recommended? Is it either engineering controls or personal equipment or are there standards set that would involve both?

Mr. KRONEBUSCH. The question of either/or arises as to which you use as the primary method. And OSHA has required that engineering controls be used first as the primary method to the extent feasible.

In many circumstances it is going to be necessary to use both, but the regulatory disputes over the last dozen years have focused on the issue of whether the primary control should be engineering controls or whether personal protective equipment should be allowed as the primary control.

Mr. PACKARD. In your judgment, have the regulations gone in the wrong direction? Do they favor more the personal equipment or do they favor the controls, the engineering?

Mr. KRONEBUSCH. The approach has been to favor engineering controls, and that, in our judgment, is the preferred method for controlling hazards in the workplace.

Mr. PACKARD. What—you mentioned, as I recall—and I may have missed some of your other control methods— ventilation was one that I think is obvious. What are some of the other engineering controls?

Mr. KRONEBUSCH. The first kind of engineering control is to consider a substitution, to use a different chemical, for example, in a process, one that has less or fewer toxic properties.

Beyond that, you can in various ways contain a process by improving the seals, for example, where there are leaks in a process, putting barriers around a process to keep leaks from happening, and then there are various techniques for ventilation—what in the trade is called local exhaust ventilation and general dilution ventilation, where you increase the flow of air in order to reduce the levels of toxic exposure.

Mr. PACKARD. In what instances would personal equipment be more effective than engineering controls? Are there some specific instances where you would see that the engineering controls would not be as effective as personal protective equipment? Mr. Gough?

Mr. GOUGH. Well, I think the—there are places where personal protective equipment, particularly respirators, are appropriate. For instance, if there is a process such as unloading a chemical where a small number of people are involved over a very short period of time, and where the use of the respirators can be closely supervised, and where the cost of—where substitution is impossible and the costs of containment or ventilation would be prohibitive—I think in those circumstances protective equipment is an appropriate way to go.

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Mr. PACKARD. In your judgment, how well do individual firms and companies follow instructions or recommendations as it relates to personal protective equipment?

Mr. GOUGH. On the OTA report that I mentioned we have some data with numbers, and this is my memory now, but, as I recall, in about a quarter of the workplaces where workers were exposed to greater than the acceptable limits of toxic chemicals, in about a quarter of those workplaces the respirator program was insufficient. Either the respirators were not worn, they weren't properly maintained, or they--inappropriate respirators had been selected for the job. So it is—I mean, it depends: Is a 25 percent failure rate bad or really bad?

Mr. PACKARD. Do you attribute in your studies of those failure rates—do you attribute that to lack of enforcement activities and efforts and training and teaching efforts by the company or do you attribute it to individual neglect by the workers?

Mr. GOUGH. We didn't go into that detail. I think companies play a major role in this, because it's—in a number of surveys which are again referenced in our report—it's only the very largest companies with quite well-developed health and safety programs and professionals who supervise these programs where the respirator programs are judged to be topnotch.

Mr. PACKARD. Let me give you an illustration of my own.

Mr. GOUGH. OK.

Mr. PACKARD. That might indicate that individuals sometimes are as responsible as companies, and I use myself as a bad example.

I was painting high equipment, high power lines, across the Columbia River, working my way through school, and was paid on the basis of the work completed, not just an hour—in other words, a bonus was attached to an hourly wage. I didn't even bother to use my safety belt on those high power lines, simply because they inhibited my ability to get work done. And when I'd get into bridge work, painting bridge work—we're talking about painters—painting of bridge work with spray guns in areas where it was difficult to use the brush, I wouldn't use a respirator because it was so cumbersome to get around and move. And it cut back on my income.

Is that a major problem?

Mr. GOUGH. It certainly is.

Mr. PACKARD. The company would have been sued if I had had a problem.

Mr. GOUGH. But, on the other hand, I hate to use the word "fault" and "blame" in a situation. What you're expressing is a common complaint of people who are burdened with personal protective equipment—that it does slow them down; it makes—sometimes makes their job more difficult.

One of the—we're not talking about this, but hearing protectors oftentimes do a real good job, so you can't hear a shouted warning, which increases your risk in the workplace.

And certainly it's a shared responsibility, but you've put your finger on one of the real problems.

Mr. PACKARD. Well, we're—and you can extend that, of course, into multitudes of hazardous areas. Painting is certainly not as hazardous as some of the other areas in terms of personal health,

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and yet, if a person is called upon to choose between paying the rent and feeding their children, or the wearing of protective mechanisms or protecting their long-term health—and many of these things are long term; you don't have immediate reactions—they're going to choose more often than not to get a bigger paycheck, and then when the long-term effects accumulate to the point where they've got a serious health problem that then affects their paycheck, because they may not be able to work or may not be able to survive, then, of course, they look to the courts or they look to the companies for some kind of remedial action.

And that's a dilemma that I see in this whole process that I have not heard today nor yesterday, nor in all the other hearings that I've attended with black lung and with asbestosis and other similar problems—I've not heard good answers that will find solutions to that, and that's of great concern to me.

Excuse me. Let me get to NIOSH, Dr. Baker.

The statement was made by Mr. Gough that the implementation of recommendations and the followingup of studies, and so forth, are slow and cumbersome. I'd be interested in your response as to how OSHA—or, rather, how NIOSH does set up their study programs and how they develop their recommendations, and to what extent you feel that OSHA is implementing your recommendations in a timely fashion.

Dr. BAKER. One aspect of the NIOSH programs that I think relates to your question are what are called health hazard evaluations, and these are specific worksite investigations that are performed at the request of either employers or employees, and in the past year a number of studies have related specifically to neurotoxic substances in the workplace.

The way these take place is the request is received by NIOSH and the team goes out to the actual worksite, goes into the plant, examines the workers directly with a physician, has an industrial hygienist to evaluate the environment, and then makes an assessment whether or not there's a hazard occurring there.

The specific recommendations as a result of that evaluation would then go back to the individual plant to be made, and it is my understanding—again, I've only worked with NIOSH for a short time—that efforts are made, also, to see to what extent those recommendations are followed up on.

It's also my understanding that the recommendations are made available to the OSHA offices in the area, that they can follow up on them as well, but, again, I should be corrected by other people who know more precisely about the process.

Mr. PACKARD. How well does OSHA, in your judgment, accept your recommendations and implement them?

Dr. BAKER. Again, I would have to beg ignorance, having only worked for a short time with NIOSH. My colleague, Mr. Lemen, I'm sure, having worked there longer and being more experienced in these things, may wish to add something.

Mr. VOLKMER. If you're going to—it's all right, but first identify yourself for the record, so that the young lady there [referring to the verbatim reporter]——

Mr. LEMEN. My name is Richard Lemen, and I'm Director of the Division of Standards Development and Technology Transfer.

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I might just add to what Dr. Baker has said. We do make recommendations to OSHA and we also make recommendations to the Mine Safety and Health Administration. And we have made a number of recommendations over the years.

Our basis in making recommendations is to address the science. It's then OSHA's responsibility to take that further, look at the economic impact, and to look at other technical feasibilities in implementing the standard.

We have worked very closely with OSHA in their Standards Development Program. I think that, you know, we have sent some 116 criteria documents to OSHA, of which 7 have been implemented into full-fledged standards.

I would say that our working relationship with them in helping them to develop standards is a very good relationship. I think maybe Mr. Tyson can speak further on this, but it takes them considerable amount of time to develop the economic analysis and technical feasibility in implementing these standards, and we have worked closely with them in doing so.

Mr. PACKARD. Mr. Lemen—is it?

Mr. LEMEN. Lemen.

Mr. PACKARD. Lemen.

The—NIOSH has got the health hazard program in which they go into the workplace to assist in their studies. Also, I understand OSHA goes into the workplace, also, to conduct their own inspections. Is there an overlap there? Is there ever times when you go to the same workplace and, if so, do you—I'd be interested to know what kind of an evaluation independent of one another you come out with and how they may correspond. Do you have experience in that area?

Mr. LEMEN. Yes. NIOSH's program of health hazard evaluations was designed more as a scientific investigation in new areas that we did not have previous experience in. OSHA goes into the workplace in a compliance fashion. If OSHA is in a workplace, we then will defer our action unless we have consulted with OSHA before going into that workplace. If we go into a workplace in a health hazard evaluation and see that it's really something that is a compliance problem, we will refer that to OSHA. Our main impetus in our health hazard evaluation program is to learn new things and to evaluate new or unknown situations. So there is relatively little overlap, in my opinion, between the two types of entrances into the workplace.

Mr. PACKARD. Thank you.

Mr. Tyson, how does OSHA set standards?

Mr. TYSON. Boy, that's a $64,000 question. [Laughter.]

Mr. PACKARD. What information do you need, do you use?

Mr. TYSON. There is an evolving process, and I say evolving because it seems like every new court decision that comes down changes the rules on us, but basically we start in many cases from evidence like that provided from NIOSH or from other outside sources, that would indicate to us that there is a potential problem with respect to a certain toxic substance or in a certain work practice. And since we're talking about health standards here, I'll confine my comments to that area.

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We would then have to take that issue, that problem, and weigh it against all the other issues and problems with respect to other toxic substances and determine from a priority standpoint which substances we should look at first.

To do that, we look at a number of things. The NIOSH recommendation is a part of that. They will tell us which substances as a result of testing—usually that testing is done in animals—seem to present the greatest problem to human health. But that's one piece of the equation. The other pieces that have to be fitted together are what number of employees are likely to be exposed to that substance and at what levels those employees are exposed to that substance. And from that, we'll make a determination where the greatest problems are and where we need to direct our resources.

But as you go through the process, there are a number of hurdles along the way. The most difficult of those is the requirement that we determine a significant risk, determine that a significant risk exists before we can regulate. And the father of the issue of significant risk is the 1980 Supreme Court case involving the benzene standard. And the benzene standard, OSHA starting way back in 1974 began work on the benzene standard on the basis of new data on the carcinogenicity of benzene. OSHA applied a policy at that time that there was no safe level of exposure to a carcinogen and attempted to regulate on the basis of that policy. So they made the determination that benzene was a potential carcinogen and that, therefore, it should be regulated at the lowest level feasible and promulgated a standard to do that.

That standard was challenged in the courts. It got up to the Supreme Court. The Supreme Court said: no, you can't do business that way. You have to determine that a significant risk exists in the workplace in the real world before you can start regulating, and your regulation must take into account that risk and must do something to reduce that risk. And you've got to be able to prove that.

That case started, or at least did a whole lot for a fledging science called risk assessment. And risk assessment is an attempt to try to quantify the level of risk that a human would be subjected to at different levels of exposure to a toxic substance. The way that risk assessment is done is usually to take animal data with respect to the dosage the animal is given, the amount of time, and the body weight of that animal, and extrapolate that into human data and make a comparison. And, therefore, you can make a determination, at least with some indication of confidence, that the same exposure in humans would have the same type of problem.

Mr. PACKARD. Is there any followup on that process to determine human experience?

Mr. TYSON. Often in our regulatory process we have human data as well. We have human data with respect to asbestos, a great of human data with respect to asbestos. We have human data with respect to benzene.

Mr. PACKARD. Does that human experience over a period of time—is that translated into reregulations or reevaluating current regulations?

Mr. TYSON. Yes, sir; it is. As a matter of fact, asbestos is a good example of that. We are now going to do our third regulation of

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asbestos. Each time we have found, as a result of additional data, primarily human data, that we need to lower that level.

Mr. PACKARD. How long of a time period normally elapses between—or from the time that you start or receive information or data from other agencies and the time that regulation is ultimately implemented?

Mr. TYSON. Congressman, it can take years and years.

Mr. PACKARD. Does it usually take years and years?

Mr. TYSON. It usually takes many years.

Mr. PACKARD. I've heard that it takes as much as 10 years sometimes.

Mr. TYSON. With benzene, for example——

Mr. PACKARD. What does that do for——

Mr. TYSON [continuing]. We're just about to get another proposal out on benzene, and we first started on it in 1974.

Mr. PACKARD. What does that do as far as exposure to liability for both the agencies that we, the Federal Government, provides or the private sector that has to deal with the effects of neurotoxins or any other toxic agents?

Mr. TYSON. There are liability issues today, and I am fortunate to be able to say this: OSHA has not been subjected to that liability, nor has any other Government agency that I'm aware of. However, there are a number of cases involving employer liability as a result of knowingly exposing employees to the substances.

Mr. PACKARD. I think the trend, though, is for agencies to be looked upon for not regulating or not providing adequate direction as being exposed now to the liability question.

Let me go also to the other side of the coin.

Mr. TYSON. Yes.

Mr. PACKARD. Much has been said in the industry of overregulation, onerous and useless regulation by OSHA. I also sympathize with that problem. Have you ever looked at regulation in terms of relaxing or changing or finding that some of your regulation is either not applicable or obsolete or not useful, and, therefore, changing that regulation in the direction of relaxing on the private sector where there is regulation that is not really effective?

Mr. TYSON. We have, as a matter of fact, a requirement to do exactly that as a result of the Regulatory Flexibility Act, an act of Congress I think 3 or 4 years ago, maybe longer than that, that requires us to periodically review all regulations currently in existence to determine whether or not they're still necessary. That's a layperson's version of the exact language.

The result of that has been the review of a few OSHA regulations in the health area. We do a great number of reviews in the safety area to determine whether or not those standards still are appropriate, and we find most often in the safety area that we're dealing with standards that really reflect back to 1940's and 1950's technology, and obviously technology has changed in that era and we need to reflect the new practices and experience.

Mr. PACKARD. One last question, Mr. Chairman, if you'd permit time.

In your judgment, Dr. Baker first, is the act itself difficult to implement? What could Congress do either to provide more flexibility

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or to provide better guidelines in the Act itself to bring about what needs to happen that is now not happening?

Dr. BAKER. Again, I have a limited knowledge of the act, just as a result of having come to work for the Government recently. But in my personal view, the act is quite adequate. It's viewed, I think, both in this country and in other countries around the world as a very significant, innovative, forward-thinking piece of legislation, and, therefore, amending the act or changing it in some way seems to be, in my view, not desirable at this time.

Mr. PACKARD. Are you, then, suggesting that perhaps maybe the way it's being implemented might not be the better way to go?

Dr. BAKER. That seems more appropriate, and, again, it's very difficult for me to be more specific about that without understanding the regulatory process.

Mr. PACKARD. Thank you.

Mr. Tyson, I'd like your response on it.

Mr. TYSON. I'm also not going to favor changing the act, but even in OSHA's most active regulatory period, where almost all of the Agency's resources, to the detriment of other parts of the Agency, I would imagine, were devoted to the promulgation of health standards. OSHA was able to get out some six standards in 4 years, two of which I think were subsequently struck down by the courts. So there's only so much that you can get out of the system, and I think a lot of that is the result of the process that we have to go through.

A better approach, and the approach that we've taken recently, is to try to approach the issue from a generic standpoint, and the second panel today is to talk about the Hazard Communication Standard which I think is a very significant piece of regulatory activity which will approach this issue from that generic standpoint, rather than the substance-by-substance approach, which is extremely time consuming and will put us in a situation where we'll never be able to catch up.

Mr. PACKARD. Mr. Kronebusch?

Mr. KRONEBUSCH. One area that we discovered in the course of doing our report has been just touched upon by Mr. Tyson—is that the OSHA regulatory process has lagged considerably behind professional recommendations concerning toxic exposures in the workplace. And, of course, it's within Congress' prerogative to change the OSHA law. It may or may not be desirable to do that, but somehow we need to find some way to get our regulatory agencies up to speed, so to speak, in terms of professional recommendations. There are lots of companies out there that are already implementing internal exposure guidelines that are less than the current OSHA standards. Somehow we have to make that more general, and that's a difficult and thorny issue.

Mr. PACKARD. Mr. Gough?

Mr. GOUGH. Well, I would just add a specific to what Karl just said, which is that most—many of the OSHA standards were adopted soon after the creation of the agency by adopting consensus standards that had been prepared by various professional organizations. And those standards were written in 1968, and in the succeeding 17 years some of those standards have been lowered—I mean the professional organizations have said the limits should be

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lowered; in other cases they've said they should be raised because the hazards weren't so great.

And, yet, to revise—for OSHA to change its regulations to come in line with the professional recommendations requires a full rulemaking procedure, which takes years and years and years. And I don't know if that requires a change in the law or if it can be a change in OSHA, or what, but it seems to me that a quicker response—either positive or negative—to professional recommendations would help protect the safety, the health and safety of workers.

Mr. PACKARD. Thank you.

There's many other questions that could be asked, but I'll relinquish my time.

Mr. VOLKMER. We'll give you more time later, because this is very interesting.

Mr. PACKARD. Yes.

Mr. VOLKMER. Your questions have been very good.

I don't know where to start because I've got quite a few areas I'd like to cover, and I just heard a word used that I want to know what you mean when you say "thorny." [Laughter.]

OK? What did you mean?

Mr. KRONEBUSCH. Oh, just that it's a difficult area for——

Mr. VOLKMER. Controversial?

Mr. KRONEBUSCH [continuing]. Legislation and controversy, yes.

Mr. VOLKMER. Political?

Mr. KRONEBUSCH. It sure will be political——

Mr. VOLKMER. Yesterday we had testimony that, you know, the area here we're concerned about is a basic political area.

I guess I could ask Mr. Tyson one thing right off at the beginning. Any regulation that you would propose to be changed, a changed regulation or an overall revamping of your standards, it has to go over to OMB; does it not?

Mr. TYSON. Every regulation does, yes.

Mr. VOLKMER. Every regulation goes over there. And you have no—and there's no timeframe in which OMB has to act on it?

Mr. TYSON. The timeframe is 10 days for what's considered to be a minor rule. If I understand, if I recall correctly, that means cost of under $100 million—and 30 days for a major rule, and they are required to get back to us within that timeframe on their recommendations.

Mr. VOLKMER. Do you usually hear from them within that timeframe?

Mr. TYSON. We usually hear something; yes, sir.

Mr. VOLKMER. But I mean a final action on it?

Mr. TYSON. It will be final from the standpoint that they will indicate questions that they want to have answered with respect to these costs within that timeframe.

Now we have started to do, what I've started to do, is to send drafts of the standards over to them very early in the process to allow them to become knowledgeable with the issue before it actually gets to the formal process, to try to shorten the whole thing.

Mr. VOLKMER. Before I proceed, I forgot, with Mr. Packard here—under our rules—we have some persons in the audience who wish to take photographs, and under our rules they are not permit-

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ted without unanimous consent. So at this time I'll ask unanimous consent. Without objection, it will be so ordered, so those who wish to do so, go ahead and do so.

We got that out of the way.

Mr. TYSON. It was unanimous.

Mr. VOLKMER. That's one way to handle it.

Now OSHA adopted the first standards in 1971.

Mr. TYSON. Yes, sir.

Mr. VOLKMER. And used the recommendations of the American Conference of Government and Industrial Hygienists. Since that time that conference has adopted voluntary standards for 200 more substances than OSHA regulates and has considerably changed its recommended exposure levels for a number of other substances.

In addition, OSHA's own standards division, NIOSH, has recommended better standards for many substances for the last 10 to 12 years. Yet OSHA has refused or has failed to act on these recommendations.

Now my question is, is it going to be necessary for Congress to require OSHA to respond to NIOSH recommendations within a set period of time or is OSHA going to be able to do this on its own in a reasonable—and in my question I'd say a reasonable time, I'd say within the shortest period of time possible?

Mr. TYSON. The issue will always turn there, Mr. Chairman, on the speed at which the substances come to us, and that will determine how much we're able to put out the end of the pipe. We only have some control over the process because of the other issues that we have to consider and the requirements of the Administrative Procedure Act and other parts of the OSH Act.

I think that I would recommend a different approach, and it is the approach that we're attempting to initiate now. And that is to look at this issue from a generic standpoint. I don't believe that any Federal agency—be it OSHA, EPA, NIOSH, or any other—is going to be able to go through a regulatory process on a substance-by-substance approach and be able to keep pace with the new data that keeps coming out and increasing exponentially every year on new health effects and findings with respect to these substances, and new substances that are introduced in the workplace every year. We're looking at 3,000 new chemicals a year that go into the workplace.

Mr. VOLKMER. Personally, I quite agree with you. If you can develop generic standards, it would be the best way to go. Does NIOSH agree with that?

Mr. LEMEN. Yes, we would. As a matter of fact, we have in the past supported OSHA very strongly in the area of generic standards. We have recently submitted to OSHA a criteria document in the area of the manufacturing of paint and allied coatings products, which recommends a generic approach to the whole painting industry, and we would like to see this type of approach go further. We've worked with OSHA in the development of their carcinogen policy, their hazard communication rule, their respirator rules, and we strongly support that approach.

Mr. VOLKMER. Now my—and this has nothing to do personally with you, Mr. Tyson; I am sure you haven't been there 14 years in your position, have you?

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Mr. TYSON. No, sir; I have not.

Mr. VOLKMER. But, you know, I've been informed that NIOSH for the last 14 years has been recommending that substances be added, and OSHA just hasn't done anything.

Mr. TYSON. It hasn't done enough.

Mr. VOLKMER. Very little. Let's put it that way.

Mr. TYSON. I think the numbers that were mentioned earlier was 14 out of 120, or something like that. It's far below the number that had been sent over; no question.

Mr. VOLKMER. You know, you look at it from our side, and those who are not may be completely familiar with the total bureaucratic process that has to be followed, and it appears somebody's dragging their feet. It leads to the question, Do we really want it done, you know?

And so we come down on that side, and I'm not condemning you as an individual, you understand that, but some of us feel that perhaps nothing really started moving until there was a—well, I've got a copy of a draft memo from 1983 that was—I think has had a lot of publicity, and it was just a draft memo about somebody saying maybe we ought to just let them all die and forget about them, because they're so old. And that, as you know——

Mr. TYSON. Let me respond to——

Mr. VOLKMER. You're quite familiar with that memo.

Mr. TYSON. Yes, sir.

Mr. VOLKMER. And, you know—so when you see things like that, that comes from within—no matter whether it was a draft, it still comes in-house, and somebody said that. And so now we look from 1983 until now, and we see, hey, they are dormant, are they not?

Mr. TYSON. They're not moving very quickly, but there are a number of reasons for that. And I'd like to address that, what we call a dormant standards issue, with a little bit of background. The action that that was generated to try to control—or that's really the wrong terminology—respond to—was a situation that, when Thorne Auchter came onboard, which would have been 1982, I guess, he found that the health standards people were working on a whole lot of different things or had rulemakings at least started from years back, and it was uncertain as to where any of those stood and where the priorities should lie.

Those rulemakings were initiated in large part as a result of the NIOSH criteria documents that had been sent over to OSHA in the 19—late 1970's. And in an attempt to try to get some sort of handle on those, OSHA, because it was a fairly easy thing to do, started—at least you can say they started—a regulatory process, and that meant that they either put an Advanced Notice of Proposed Rulemaking in the Federal Register or a request for information. Those are relatively easy things to do. You can write up one of those within a matter of a month or so and get it published. That's only just the very, very beginning of the regulatory process.

So what we did is get kind of a table of everything that was on the plate in health standards and then we asked NIOSH to go through that and determine which of those were the most important, and they responded quite adequately, in our view, and gave us the list of 51, I think, of those that they felt deserved further regulatory action.

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I, in turn, took that list of 51 and incorporated into the OSHA Regulatory Plan for the whole Administration as things that we were going to be working on.

I mean, when the facts are presented, it doesn't appear to be quite as villainous as maybe a very quick view would indicate.

Mr. VOLKMER. Are we assuming, then, that the other ones that were originally recommended out of the 100 and—I believe it was 116—that, even though they had been recommended by NIOSH, that NIOSH, Mr. Lemen, has backed up and says, no, these really aren't worthy of regulation?

Mr. TYSON. Well, what—NIOSH took those 115 substances and put them in three categories. The first category were those that it believed that we should proceed with the rulemaking. The second category—and I will quote from the letter from the Director of NIOSH, Don Millar, Dr. Don Millar—the second category, which was 18 substances, are those which the rulemaking process should be deferred, pending the outcome of some studies that were currently underway. The third category, which was 46 substances, was substances for which insufficient information is available at this time on which to base a new or revised OSHA standard.

Mr. VOLKMER. Now——

Mr. TYSON. I'd be happy to submit that for the record.

Mr. VOLKMER. All right.

[Material to be supplied follows:]

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Group 1 Substances

Alkanes
- Heptane
- Octane
- Pentane

Allyl chloride
Ammonia
Arsine
Benzyl chloride
Beryllium
1, 3 -Butadiene
n-Butyl alcohol
Cadmium
Carbon monoxide
Carbon tetrachloride
Chlorobenzene
Chloroform
Chromic acide
Chromium (VI)
Diazomethane
1,2-Dichloroethane (ethylene dichloride)
Diethylamine
Dioxane
Epichlorohydrin
2-Ethoxyethyl acetate
Ethyl acrylate
Hydroquinone
Isopropyl alcohol
Ketones
- Cyclohexanone
- Hexone (methyl isobutyl ketone)
- Mesityl oxide
- 5-Methyl-3-heptanone (methylisoamyl ketone)
- 2-Pentanone (methyl n-propyl ketone)

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Mercury, inorganic
2-methoxyethyl acetate
Methyl alcohol
4,4´-Methylenebis-(2-chloroaniline) (MOCA)
Methyl iodide
Nickel, inorganic
Pesticides, generic
Polychlorinated biphenyls
Refined petroleum solvents
Silica, crystalline
Styrene
Sulfur dioxide
1,1,2,2-Tetrachloroethane
Tetrachoroethylene (perchloroethylene)
Toluene
1,1,1- Trichloroethane
1,1,2-Trichloroethane
Trichloroethylene
Vinyl bromide
Vinyl chloride

Group 2 Substances

Acetylene tetrabromide
Acrolein
Biphenyl
Bromoform
tert-Butyl alcohol
alpha-Chloroacetophenone
o-Dichlorobenzene
Dimethylamine
Ethyl benzene
Ethyl bromide
Ethyl formate
Furfuryl alcohol
Methyl methacrylate

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Ethyl formate
Furfuryl alcohol
Methyl methacrylate
p-Nitroaniline
Propylene dichloride
Sulfuric acid

1,2,3-Trichloropropane
Vinyl toluene

Group 3 Substances

n-Amyl acetate
sec-Amyl acetate
n-Butyl acetate
sec-Butyl acetate
tert-Butyl acetate
sec-Butyl alcohol
p-tert-Butyltoluene
Camphor (synthetic)
Chloroacetaldehyde
Chlorobromomethane
Cumene
Cyclohexane
Cyclohexanol
1,2,-Dichloroethylene

Difluorodibromomethane
Ethyl acetate
Ethyl-sec-amyl ketone
Ethyl butyl ketone
Hexachloronaphthalene
sec-Hexyl acetate

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Ketones
2-Butanone (MEK)
Diacetone alcohol
Methyl-n-amyl ketone
Methyl acetate
Methyl acrylate
Methylcyclohexane
Methyl isobutyl carbinol
Naphtha, coal tar
Ozone
Pival
Polyvinyl chloride
n-Propyl acetate
Propyl alcohol
Silica, amorphous fused
Styrene, alpha-methyl
Terphenyls

1,1,1,2-Tetrachloro-2,2-difluoroethane
1,1,2,2-Tetrachloro-1,2-difluoroethane
1,1,2-Trichloro-1,2,2-Trifluoroethane
Trifluorobromomethane
Turpentine

Mr. VOLKMER. Twenty—as I have been informed, 26 of the 51 that you're going to take some action on—well, first, what action have you taken on those 51?

Mr. TYSON. If you're talking about—OK—of those 51, I think we have initiated some form of action on two of those, and I'm not going to try to stand up and say that's a great record. I'm just going to reflect reality.

Mr. VOLKMER. I don't think you can. I just don't think you can—2 out of 51. I mean, that's—if we take two a year, that's 25 years——

Mr. TYSON. Now there are going to be new ones coming on——

Mr. VOLKMER [continuing]. On 51. We've got several thousand out there.

Mr. TYSON. You're absolutely right; yes, sir.

Mr. VOLKMER. I mean——

Mr. TYSON. Even if we took 25 a year, we will quickly fall behind at any pace.

Mr. VOLKMER. That's correct.

Now the question is, I guess Congress is going to have to do something.

Mr. TYSON. Well——

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Mr. VOLKMER. Look at it a lot more closely than we have been or else—you know, it gets back to—I started to save this, but I think—where did that information go? Here it is.

I made some notes here from what I learned yesterday. See if you—correct—you correct me if my thinking is wrong on this.

Yesterday we had testimony about a substance known as BHMH that had been used in Texas—started, I think, around 1977 and it was used up until 1979 in the manufacturing of reinforced bathtubs. No, it was used only a couple of weeks, in 1979—several weeks.

Employees, within a few weeks, started having dizziness, pins and needles, muscle weaknesses, incontinence, memory loss, disturbed vision. So we withdrew it.

If I was a manufacturer today and I decided I'm going to go ahead and use that stuff, because I can use it in my manufacturing process, and to heck with the employees, can you stop me?

Mr. TYSON. What we can do, and will do, starting May 25 of next year, is require you to make all the health information available with respect to that substance, availabl to the employees that are going to be exposed to it; put hazard warning labels on any containers that the employees are going to be using to contain this substance; and train the employees in the hazards associated with it and how to protect themselves.

Regardless of what a substance is, if there are adverse health effects reported, the employers got to make those known to the employee. That's the Hazard Communication Standard in a nutshell.

Mr. VOLKMER. All right. Now—but I would be able to use with those——

Mr. TYSON. You would be able to use it. No, sir; we do not ban substances, no.

Mr. VOLKMER. Even though it has these known effects?

Mr. TYSON. Right. Now you would have to do a premarketing process through EPA's TSCA office. I'm not sure exactly how that works, but——

Mr. VOLKMER. We went with them, too. That's where it came from.

Mr. TYSON. Was the answer that they could do it?

Mr. VOLKMER. No. The answer is that, basically, under theirs they can require no testing, or et cetera, except that all the firm has to do is report to them any testing data that they have, but I'm not going to do any testing.

Mr. TYSON. Right. But now under——

Mr. VOLKMER. Right? Is that right? You've got 700-and-some here that have been reported to TSCA; no data. You don't do any testing.

Mr. GOUGH. That's right.

Mr. TYSON. Now under our standard, under the Hazards Communication Standard, it's not tests that that employer does; it's any test that anybody does that are reported. All such tests have to be reported.

Mr. VOLKMER. All right.

Mr. TYSON. And if there's evidence in the literature, then the employer is required to make that information available to the employee.

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Mr. VOLKMER. I've been informed that the only safe use you can have with BHMH is with a total coverage suit that covers the total body, and you don't have any such requirement.

Mr. TYSON. We might. We don't with respect to that substance.

Mr. VOLKMER. I mean, if I want to start using it today, you understand the problem?

Mr. TYSON. I understand your question, and I have to answer in the affirmative.

Mr. VOLKMER. That's a no?

Mr. TYSON. Yes, sir.

Mr. VOLKMER. Then we get to another one. We also had testimony about AETT, which is musk tetralene, a fragrance preparation that's in soaps. I guess we all wash. Creams—we use in on skin. Perfumes—a lot of ladies do that. Aftershave lotion—a lot of us men do that. Detergents. Used from 1955 to 1977, withdrawn in 1977. The same thing applies. The only tests were done on rats.

Mr. TYSON. Well——

Mr. VOLKMER. Those tests that come in, what are you going to do when the tests show that they show signs of irritability, some memory loss, and things like that?

Mr. TYSON. Under the Hazard Communication, those effects would have to be reported. They would have to be made known to the employee.

Mr. VOLKMER. Be known to the employee?

Mr. TYSON. Right.

Mr. VOLKMER. Put on a little thing that—I guess if you could word it like we had some testimony yesterday, I have some wording, if I can find them.

You mean stuff like this [holding up paper showing label]?

"Dioxin polyethylene enamel activator." You have a warning on there, but it really doesn't warn about the nerve damages and stuff like that, memory loss and things like that.

Do you understand? It's almost useless warnings.

Mr. TYSON. Yes. Then that warning probably would not be adequate under the OSHA's Hazard Communication Standard.

I was looking to see if I had an example of some of the requirements under our Hazard Communication Standard. I could get those to you and submit them for the record.

Mr. VOLKMER. But with that warning, I could still use it in a manufacturing process?

Mr. TYSON. Right. The only way that we can have any effect on it with respect to the level of employee exposure is if we have a regulation that covers it specifically or if we can demonstrate that it is a generally recognized hazard in the industry. Under that situation, we can use what's called a general duty clause of OSHA, or section 5(a)(1) of the Act, and in that respect cause the employer either to reduce exposure to employees to levels which are considered safe or conceivably to prevent its use completely. But that's a fairly high burden to demonstrate that you've got a consensus of the industry that the issue or the substance is a hazardous substance.

Mr. VOLKMER. Right now we're not doing warning labels, though?

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Mr. TYSON. Well, they're not required now. There's some in place. They are required under the 22 specific standards that OSHA has promulgated since 1972. We do have warning label requirements in there.

All OSHA standards, all new OSHA health standards have to require warning labels. The Act requires us to take that into consideration in the rulemaking process; so all of those standards do have it.

Mr. VOLKMER. But it doesn't apply to all types of workers and all types of workplaces?

Mr. TYSON. The Hazard Communication Standard does not now. It only covers manufacturing. Now there will be some downstream effect. We feel quite certain that we'll get into all other workplaces, and I'll be publishing an Advance Notice of Proposed Rulemaking within 30 days, opening up the rulemaking process to expand the scope of Hazard Communication into all workplaces.

Mr. VOLKMER. I'd like to get back to the two out of the 51 just for a minute. What can we look to—a year from now, if we have another hearing, how many can we say that we've acted upon?

Mr. TYSON. Mr. Chairman, I'll be honest with you. I'll be happy if we can get those two done. The process is that burdensome.

Mr. VOLKMER. Initiate any additional?

Mr. TYSON. Conceivably we'd be able to get a couple more initiated, but you asked me if we'd be able to finish any.

Mr. VOLKMER. Mr. Lemen, is NIOSH now investigating any cases where workers have suffered from exposure to methylene chloride at levels allowed by OSHA?

Mr. LEMEN. Yes, Mr. Chairman, we are in the process of one health hazard evaluation that I'm aware of, that being at the Budd Co. in Madison Heights, MI, where we have been looking at——

Mr. TYSON. It's Ohio, isn't it?

Mr. LEMEN. I'm sorry, in Ohio—where we have been looking at, through our health hazard evaluation program, methylene chloride exposures, and we have some preliminary results that I'd be happy to submit to the committee showing the levels that we're finding in the plant and some of the findings we found in the workers in that plant.

Mr. VOLKMER. Yes, I'd like to have that data.

Mr. VOLKMER. And with that, I'd like to ask Mr. Tyson, What warnings are those workers afforded?

Mr. TYSON. Let me add a little bit more to that story. That particular case involved complaints to OSHA where we went out and did an inspection and found a few problems, but they were problems that we were unable to reach using OSHA standards currently in existence. We then requested that the employer ask NIOSH to come in and do just the evaluation that they did.

Now to answer your specific question, there are no current requirements to label for methylene chloride. I'll be issuing guidelines. They'll be circulated to our field offices for their review on Thursday of this week with respect to the handling of methylene chloride. There is some new scientific data that has come in with respect to the hazards associated with methylene chloride that would indicate a need for lowering the standard. We're evaluating

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that data, but in the meantime we're developing guidelines for safe use.

That also would be covered, though, under Hazard Communication. And after that standard does go into effect, clearly the hazardous properties of methylene chloride would have to be made known to the employees exposed to it.

Mr. VOLKMER. Now several years ago you established a generic standard for the regulation of cancer-causing substances, did you not?

Mr. TYSON. It's not exactly that, as you refer to—well, we call it Cancer Policy. And the Cancer Policy is an attempt to try to streamline the process that OSHA uses to regulate carcinogens. And what it did is try to answer some of the questions that tended to come up in almost every rulemaking process that OSHA underwent with respect to a carcinogen. It addressed such issues as the value of animal data; you know, how much it takes to make something be considered a carcinogen; and made some attempt, at least, to a prioritization of substances for action under that—under cancer policy. It's still in existence. We still use it.

Mr. VOLKMER. Have any substances been regulated under that standard?

Mr. TYSON. Ethylene oxide, formaldehyde is—we've started the process. Ethylene oxide is a final. Benzene would have been affected by that as well, because it's a leukemigen; asbestos as well—I'm forgetting the big one.

Mr. VOLKMER. Mr. Lemen, on the other hand, 51 out of the 116 substances, what activity is NIOSH doing in regard to further testings, data, et cetera, for the remainder of the categories 2 and 3?

Mr. LEMEN. On some of these, other agencies besides NIOSH are doing research projects. On the 18 that we recommend that we defer action on until that research is completed, we are monitoring that research. Some of the research is being done by the National Toxicology Program; some being done by academic institutions.

We have a system within our institute for all these chemicals that we are following on a routine basis to determine any new developments that might be—make our recommendations change, and we are prioritizing under that system the chemicals that we feel may need to have a change or make a new recommendation to OSHA in the future.

So the short answer is that we're following them, and we're doing some in-house research, and in other areas we're watching what's being done by other research agencies.

Mr. VOLKMER. When do you figure or determine the timeframe of completion of that activity, so further recommendations may or may not be made to OSHA?

Mr. LEMEN. Well, I think that's going to be an ongoing process that's going to continue for years in advance. And we will continue to monitor these and, as we do, all other chemicals. Our institute—I don't know if you're aware—is required under the Occupational Safety and Health Act to yearly provide a registry of toxic effects of chemicals, and we have maintained that registry since the beginning of NIOSH in 1971. We now have 78,000 chemicals in that registry; 6,400 of those chemicals have some neurotoxic citation to it.

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So on a routine basis, we are monitoring all 78,000 of those chemicals. We're adding at the rate of about 2,000 to 3,000 chemicals a year to that list. So it's a major effort on our institute's part to monitor the toxic effects of chemicals. And, in doing so, we monitor not only research within the United States, but research worldwide.

Mr. VOLKMER. This is all fine and good. We get it all on a computer, I suppose, but now what do we do with it after we've got it there?

Let me ask you a question that we had some discussion yesterday on, and I guess even into the area where we need more research even to determine.

When you're talking, Mr. Tyson, Dr. Baker, and others, about doing a generic standard, how are you going to do that—on a structural basis of the chemicals?

Mr. TYSON. Well, our determination with respect to the generic standard and hazard communication was that any reported adverse health effect. If there was a study showing that there was an adverse health effect, that generates all of the protections under that generic standard.

Mr. VOLKMER. A study done or test results—would that qualify, also?

Mr. TYSON. Yes, sir.

Mr. VOLKMER. I am finding in yesterday's and today's hearing that we're not doing that many studies, and there aren't very many tests.

Mr. TYSON. There is a great deal of activity undergoing now, not just by Government, but by private industry and by labor organizations, testing the toxicity—and, obviously, your interest is in neurotoxicity—that and carcinogenicity of substances. All of those results have to be reported to the Toxic Substances Control—I guess they call themselves the Administration, or whatever their title is. Under TSCA, that has to be reported, and it gets in the literature.

At one time the list that Mr. Lemen mentioned earlier—we had one time considered triggering the Hazard Communication Standard by using that list, what we call the RTECS list, Registry of Toxic Substances. But we took a look at the RTEX list, and there are substances on there which, in any normal way of viewing, would not really be toxic. I think salt's on there and sugar and some things like that. So we found, also, that because of the delay in things appearing on that RTECS list that it was a better approach (and this approach was validated by the third circuit in their review of the Standard) to require the evaluation be done by the employer and any adverse health effects that are reported in the literature have to be made available, and it triggers the whole process.

Mr. VOLKMER. All right. We've got 6,400 on the registry that basically are neurotoxins to some degree. Right now, Mr. Lemen and Mr. Tyson, can you tell me how many studies are being done and how many manufacturing facilities in regard to those 6,400?

Mr. TYSON. I can't tell you. Ask Mr. Lemen if he's got any idea. I doubt if we would know, because the reporting requirement is——

Mr. VOLKMER. By OSHA or by NIOSH.

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Mr. TYSON. We—OSHA does no studies. We do not do any basic research. We take studies that have been done by other organizations—NIOSH is one of the primary organizations we look to; they are the research arm—and then from that, either take regulatory or other action.

Mr. LEMEN. We have—I'll ask Dr. Baker also to respond to this—but we have had in the past few years some 70 health hazard evaluations on neurotoxic substances that do appear on the list, as well as we do have ongoing research within the institute that I think Dr. Baker is prepared to discuss.

Mr. VOLKMER. Yes, I'd like to know.

Dr. BAKER. If we started off with just the hazard evaluations that I referred to previously, there are about 30 or 35 of those hazard evaluations. How many actual substances are involved in those, it's very difficult to say. In most workplaces people would be working with 10, 15, 20 different neurotoxic substances in a particular site. So to come up with a meaningful number, you multiply the number of worksites times the number of those substances.

That's a bit misleading because in most sites certain small number of compounds are used over and over again. And, therefore, a lot of the research that's being done attempts to focus on the most commonly used substances, where we do have evidence of toxicity.

Even though the list is long in terms of numbers, there are many of the substances that are listed as being neurotoxic that are neurotoxic because they cause irritant effects, and these certainly are less concern than those that would have structural damage to the brain.

So what's been done, both in the in-house research —and that constitutes about $1 million of expenditure annually on the part of NIOSH—and extramural research, which also is about a million dollars a year. We try to focus on the most important substances and try to do so in ways that would allow us to generalize to other substances that are on that list. Obviously, it's impossible to look at that many chemicals individually.

What we can then do is, based on our knowledge of those substances that we study, make recommendations for others on that list based on so-called structure activity relationships or chemical similarities. That would then lead us to generic standards again.

It would be appropriate, based on that line of reasoning, to develop a general standard for, say, organic solvents. That's a very large hetereogenous group of chemicals which contain many different recommendations, and NIOSH has already put forward criteria documents in the area of solvents in the past with specific recommendations on that.

So, in my view, it's not necessary that we go at each individual substance as long as we pick our substances appropriately for those that do have the most hazard potential and are the most widely used.

Mr. VOLKMER. But how many are we doing?

Dr. BAKER. How many—doing in what way?

Mr. VOLKMER. Doing a study or in-house, in-the-plant observations, workups. How many are we doing? Testing, whatever have you, animal laboratory tests, whatever?

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Dr. BAKER. In terms of the actual chemicals, I would—I really can't say because the information I have doesn't list it in that way. It would be my guess that we're talking about 50 to 100 different chemicals in terms of substances that affect the nervous system. Those tend to be the most important ones, the most widely used.

Again, the figures that I raised earlier were that between, say, 10 and 25 percent of the substances, the 60,000 or so substances, may have effects on the nervous system. That would then mean something like 6,000 to 12,000.

But many of those substances are on that list because they irritate the nervous system, either the sensory apparatus, and so forth—and those, I think, are in some ways already dealt with by current thinking.

It's important for us now to look at those where our knowledge is lacking and where standards may not be high enough—may not be low enough to be protected; excuse me.

Mr. VOLKMER. Isn't it true that in many of these areas where there are known neurotoxins that OSHA standards are not low enough, the exposure level is not low enough?

Dr. BAKER. That's correct. That's in our testimony. NIOSH has in many instances recommended lower standards than currently NIOSH protection levels, permissible exposure limit.

Mr. VOLKMER. Is there not significant risk to employees for long-time exposure to some of these neurotoxins?

Dr. BAKER. If they're exposed to currently accepted permissible exposure limits, I would say yes.

Mr. TYSON. That brings an important point up, though. We have to determine what the actual exposures are in order to make that finding.

Mr. VOLKMER. Well, I agree that, in order to come to the conclusion that we've got people out there that are—even with information that we presently know about the chemical, that with the exposure, if they have certain exposure, they're going to have resulting injury, and I agree that you have to know what the exposure rate is. I won't deny that.

But even the potential out there of not knowing—we don't know, do you?

Mr. TYSON. Oh, yes, we do.

Mr. VOLKMER. Do you know the exposure level of all employees in all manufacturing plants——

Mr. TYSON. Oh, of course not.

Mr. VOLKMER [continuing]. Of these neurotoxins that we know? There are 6,400 of them; right?

Mr. LEMEN. Well, there's 6,400 chemicals in our registry of toxic effects that have some citation.

Mr. VOLKMER. Right.

Mr. TYSON. Now we've got—I've got a list of the standards that OSHA does have that have neurotoxic effects. We've conducted some 26,000 workplace samples of these neurotoxins for which we do have existing standards, and, therefore, we will know the level in those workplaces of exposure to those 26,000—as a result of those 26,000 different tests. That's not 26,000 substances; I don't want to mislead you.

Mr. VOLKMER. Right.

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Mr. TYSON. We're talking about a list of maybe 150 substances. But that's an indication of the picture that we do have of the actual exposures in there.

Now if we went to a rulemaking process, we would actually contract out to go out and make measurements, either through a private contractor, if they're looking at employer data or union data, to find out what actual exposures were with respect to a specific substance.

Mr. VOLKMER. Do you mean the 20-some-thousand monitoring that you've done you do not know with that the exposure level of those employees to those neurotoxins, those chemicals?

Mr. TYSON. Oh, yes, we do, but these are substances for which we do have current standards. Where we are developing a new standard and do not have adequate data on the actual exposure, we would contract out to try to get that data, because it's an important piece.

Mr. VOLKMER. You do not—I'm not—I'm saying for——

Mr. TYSON. I'm afraid I'm misleading you.

Mr. VOLKMER [continuing]. The present exposure levels, do you have that information?

Mr. TYSON. Yes, sir; we do with respect to those substances that OSHA does have standards. Of those 400 or so substances, 100 or so of those are neurotoxins.

Mr. VOLKMER. Right; and you know what the exposure levels in certain workplaces are as far as those neurotoxic chemicals are concerned?

Mr. TYSON. Yes.

Mr. VOLKMER. You also know what NIOSH has recommended as far as levels of exposure; correct?

Mr. TYSON. Yes, sir.

Mr. VOLKMER. Now are some of those above those levels?

Mr. TYSON. Some, but often the recommendations—and the recommendations of groups like ACGIH, which you mentioned earlier, are for a reduction of those levels but the reduction is often maybe only half. In other words, the OSHA standard may be 100 and they're recommending that we drop that standard to 50. That's really not a very significant reduction that would urge immediate action.

One example that we mentioned earlier, methylene chloride, though, is a different picture. There we're talking about a very substantial difference between the recommendation of the current OSHA standard, and, of course, that's one we're working on.

Mr. VOLKMER. What I'm concerned about is, and what I'm hearing here and basically what I heard yesterday is, that there's still—how many employees are there at, let's say, the Budd plant in Ohio that have exposure at the present time, Mr. Lemen?

Mr. LEMEN. I'd have to refer to this document, if you can give me just a second, which I said I would submit to the record.

I don't have an actual number of employees that are exposed. I can tell you the numbers of samples that were taken, and I'd be happy to submit to the record the actual numbers of employees.

Mr. VOLKMER. Well, I'd like to have it, because, in my opinion—you correct me—you tell me if I'm wrong, Mr. Tyson, Mr. Lemen, Dr. Baker—those employees are guinea pigs right now.

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Mr. TYSON. That term carries connotations far beyond what's actually happening with respect to those employees.

Mr. VOLKMER. Can you tell me that none of those employees will be adversely affected by their exposure to methylene chloride?

Mr. TYSON. I cannot tell you that; no, sir.

Mr. VOLKMER. Oh, you can't?

Mr. TYSON. But I don't think the obverse of that is that that makes them guinea pigs.

Mr. VOLKMER. Well, what are they, then?

Mr. TYSON. That makes them employees that may be subjected to exposure to a toxic substance for which OSHA has yet to regulate at a lower level. Guinea pig implies that we're intentionally picking them out to test them to see what happens to them, at least in my mind.

Mr. VOLKMER. Well, they're being tested. They're going to be tested, are they not?

Mr. TYSON. Well, we——

Mr. VOLKMER. The effects are going to followed?

Mr. TYSON. We're looking to see what's actually going on and what the——

Mr. VOLKMER. With those employees?

Mr. TYSON. Yes, sir.

Mr. VOLKMER. In that workplace?

Mr. TYSON. In that workplace.

Mr. VOLKMER. Yes.

Mr. TYSON. In my mind that's different from a guinea pig, but this is your committee. Obviously——

Mr. VOLKMER. It's a difference of opinion as to testing procedures, I suppose.

Let me ask you a basic question, philosophical.

Mr. TYSON. Yes, sir.

Mr. VOLKMER. Do you consider, or does OSHA consider, chemicals to be safe until proven unsafe?

Mr. TYSON. That's an interesting philosophical question. That's one I really haven't thought about. I would say that I personally—and I would have to speak from my own personal standpoint—would consider that any new chemical has to be viewed with some suspicion, but it's too broad a statement to say that they're guilty until proven innocent. It would depend on what that chemical is and its relationship to similar chemicals, substances with chemical makeups which are close. In fact, that's the approach that many agencies use to determine which are the targets for further research. If something has a chemical identity which is very close to another substance which is proven to cause trouble, then that one goes on the suspect list.

Mr. VOLKMER. Now in this whole process, is this— is your opinion, in trying to combat the effects of neurotoxins in the workplace, that we put more emphasis on personal protective equipment than we are on the nonuse or controlled use of the chemical?

Mr. TYSON. OSHA's priority remains that the first priority is to use engineering controls. The issue that has been addressed in recent years is to try to better determine what feasible engineering controls are possible. The difficulty that OSHA has had in many—for many years is a lot of litigation with respect to what feasible

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engineering controls need to be in place. What we're trying to do in our standards process is to better define which—you know, what is feasible.

Now where feasible engineering controls are not effective to reduce the level down to what we consider to be, you know, the exposure level that we want to get to, then you go the rest of the way with respirators. But I'm not going to advocate respirators in place of engineering controls. They're only a supplement when the engineering controls don't work.

Mr. VOLKMER [pulling out box containing respirators]. I hadn't seen one of these. I saw pictures yesterday.

Mr. TYSON. Look to see if it's got the NIOSH approval on it. [Laughter.]

Mr. VOLKMER. Pardon?

Mr. TYSON. Make sure NIOSH has approved it.

Mr. KRONEBUSCH. Mr. Chairman, you may want to attempt the shake test right now. [Laughter.]

Mr. VOLKMER. What?

Mr. KRONEBUSCH. The shake test. You hold it and shake it firmly, and if anything falls off, it's defective. [Laughter.]

Mr. VOLKMER. Do you mean if I take it like this [shaking respirator] and nothing falls out, it's OK?

Mr. KRONEBUSCH. That's only the first test.

Mr. VOLKMER. That's only what?

Mr. KRONEBUSCH. That's only the first test. As Mr. Packard pointed out earlier, the devices are extremely uncomfortable to wear, especially in hot working environments.

And as we testified, there is only limited research indicating the effectiveness of these devices.

Mr. VOLKMER. Well, that's the question I want to ask: How much testing do we do on the ability—let's take this device or this device [holding up respirators]—to filter certain individual neurotoxins in chemicals?

Mr. LEMEN. I might indicate that we do have a certification testing program within NIOSH and that we're in the process of revising that Testing Certification Program, which we have had a recommendation in to the Mine Safety and Health Administrator, which we work with in—under that regulation for the testing, and that's a regulation called 30 CFR 11.

We have had that to the Mine Safety and Health Administration for the last year waiting for their response to that. And in that, we do recommend some changes in the testing program we have, and I'd be happy, again, to provide that information to this committee, if they would like to see it.

I do want to add that I agree with the OTA people that field testing is a very important part of respirator testing, and it's something that more needs to be done in that area. And I would also agree that the use of respirators is certainly not something that NIOSH advocates as the first line of protection.

We also agree that engineering controls and substitution and administrative controls are much more appropriate way to go in preventing the neurotoxic effects of chemicals in the workplace.

Mr. VOLKMER. Now respirators don't help you if you have a skin-encroaching chemical, do they?

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Mr. TYSON. That's correct; yes, sir.

Mr. VOLKMER. It will help you warn him but not the rest. And that happens, does it not?

Mr. LEMEN. We do make recommendations, also, for other personal protective equipment such as gloves, aprons, protective clothing, et cetera.

Mr. VOLKMER. But is it not true that that respirator—any one of these—is not necessarily qualified to filter all neurotoxins of all chemicals from the air?

Dr. BAKER. Well, again, the problem is knowing all of the substances. I think that, generally speaking, the testing of the effectiveness of the device to filter chemicals out is much farther along than some of the other issues that relate to the use of respirators.

The major problem, as was alluded before, is that people don't wear them because they're uncomfortable; they don't wear them——

Mr. VOLKMER. That's pretty heavy, too.

Dr. BAKER. Right. They question their effectiveness, and they don't wear them in some situations because the general attitude in the workplace is such that they don't think it's important.

In some of the previous research work that I was involved in, we tried to do a reseach project—and it's now underway in conjunction with the painters' union—to try to determine why it is that people do or do not use these things in situations where they have been tested and found to be effective.

For the most part—again, we can always do better in this regard—the testing of the actual physical efficacy of these devices has been conducted reasonably well. There are always ways to improve that, to measure fitting, and so forth, but what tends to happen in the actual workplace is that the devices simply aren't worn for one reason or another, and it's clearly a joint issue that involves the employer and the employee.

Mr. VOLKMER. OK. I—I don't know.

Have we or you fulfilled your responsibility to the workers as long as you've gotten an approved respirator and it's recommended for use in the workplace, even though you know that that worker probably won't use it?

Mr. TYSON. Is that my question?

Mr. VOLKMER. Yes.

Mr. TYSON. Well, I've—no; we haven't fulfilled the obligation. But, then, again, OSHA standards are going to require that that respirator be used in a situation where it's appropriate for it to be worn. Their regulations are going to require that there be a complete respirator program with respect to the maintenance of the respirator, the testing of the fit of the respirator, and an assurance that the employer will enforce their use in appropriate situations. OSHA's position is that, if an employee fails to wear a respirator or any personal protective device when they're supposed to under any applicable OSHA standards, the employer has to take disciplinary action to insure that the employee does take it—right up to firing him. And we had that case come up a number of times, especially with the hard hats issue, and our position was supported.

Mr. VOLKMER. What about fining the employer?

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Mr. TYSON. We do—that's what we'll do. We will issue a citation to the employer for failing to insure that his or her employees wore the personal protective equipment or utilized the personal protective equipment that was provided for his or her use. Absolutely. We hold the employer responsible in that situation.

Mr. VOLKMER. I've just been informed that 6 months ago several labor unions petitioned OSHA for a new exposure limit for wood dust, submitted 35 studies showing adverse effects. What action have you taken on this toxic substance?

Mr. TYSON. Wood dust is an area that we're—you didn't mention, but I have a similar petition on methylene chloride, which we talked about earlier. Both of those are under evaluation by the Health Standards Director to make a determination of what the next step of action should be.

On the methylene chloride issue, I've taken the initial step of requiring guidelines and asking that the guidelines be produced, to get information out quickly on this issue. Wood dust is already covered under OSHA standards, and the question is whether or not we need to lower that exposure level.

Mr. VOLKMER. How long will it take to—several years again—to—if there is a follow-up decision made—if that decision is made, to propose regulations in regard to it? Are we looking at 5 or 10 years?

Mr. TYSON. If we initiated a rulemaking process today with respect to either wood dust or methylene chloride or anything else, a realistic expectation of going through the whole process is a year or two. It depends on the volume of the record that's produced and the issues that are associated with that substance, the degree of exposure, the number of employees that are exposed, the number of employers that have that substance in the workplace. It's a very difficult process.

Again, I would urge the committee's endorsement of the approach that OSHA is undertaking, which is to try to apply some generic standards to addressing this issue.

Mr. VOLKMER. Now the staff just mentioned that's true—not to mention that OMB has to agree, too.

Mr. TYSON. Well, actually they don't have to agree. We have to consult with them.

Mr. VOLKMER. Yeah.

But when OSHA refers to some behavioral disorders as subtle effects of exposure to chemicals, how does OSHA take into account the fact that some of these subtle effects such as slight loss of memory or feeling, concentration, coordination can lead to serious accidents and injuries at the workplace?

Mr. TYSON. It comes into consideration, but our regulatory action would have to be based upon, you know, some sort of quantifiable data in that area. And where you and I can agree that clearly that would have an effect, it's going to be difficult, very difficult, to quantify that so that we'd be able to make the kind of significant risk finding that would be necessary in order to sustain a court challenge to the standard.

Mr. VOLKMER. OK. Dr. Baker, now we know that out there right now there are chemicals with neurotoxic effects that are being used not only in the workplace, but are being used in the home,

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businesses, and every place else. And they're going to continue to be used, it appears, for at least another two or three years.

About how many illnesses and debilitation effects are we going to have in this country as a result of this in the next couple of years?

Dr. BAKER. Well, it's really impossible to estimate, unfortunately, because we don't really know how many of those sorts of things are occurring currently. There are a number of problems in this area.

First of all, these conditions are, as you discussed earlier, just becoming recognized in the terms that can be used by medical people to define these conditions.

One of the important things that we're trying to work on in NIOSH is to develop a clear set of definitions about what kinds of conditions are that we're looking at, and, therefore, be able to answer questions like yours, because it's very important not only in knowing that these are increasing or going down, but also in allowing us to specifically respond to problems when they do occur.

But right now the set of conditions is so poorly defined, the kinds of terms that you and others have been using before are the ways these are described—you know, vague memory loss, vague symptoms of irritability. There's not any real precision in describing what it is we're talking about.

That's why I think that some of the things that have occurred recently involving the World Health Organization and an attempt to try to define these conditions more precisely, and also newer tests to give us objective information about what's going on, is going to be the way to go.

There are some encouraging developments in that area. Certainly we should be going faster, in hopes that we can in two years be able to answer the question of what's going on at that time, but it's impossible to predict, in my view, what's going to happen.

Mr. VOLKMER. Are we to assume that nothing adverse is going to happen, then?

Dr. BAKER. Well, I think it's very likely that there will be significant adverse effects occurring from neurotoxic substances over the next couple of years. We know that those are occurring now. We have examples of those that have been described today.

Mr. VOLKMER. And, of course, as we had testimony yesterday, and in my mind, it's probably true that a lot of those are not being attributed to neurotoxins but personality changes and that type of thing that supposedly occur in people. Do you agree with that?

Dr. BAKER. There is clearly a lot of misinformation on the part of physicians, employees, employers in this area. These kinds of complaints often are attributed to other factors—stress, emotional problems, and so forth, and not the specific chemical substances.

There are also strong disincentives for individuals coming forward and saying that they have health problems, because of the obvious job implications that were referred to previously. So there are many reasons why we're underreporting these conditions.

A previous congressional committee focused on the issue of surveillance of occupational disease, and the point has been made at that time and elsewhere that these conditions probably are underreported to a very great extent. We just don't know the extent of the problem.

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Mr. VOLKMER. I guess my last question for you, Dr. Baker—in making recommendations to OSHA on areas, areas of standards for various chemicals, et cetera, do you ever feel frustrated in not having your recommendations followed?

Dr. BAKER. Well, I've only had the opportunity of being frustrated for 4 months. Most of my frustration is because my papers are all packed up in boxes and I can't find anything, but I know that many people who have worked in NIOSH feel that frustration, and the numbers that you've recited before are examples of that.

How far back to go? I think I should rely on Mr. Lemen for a better historical picture.

Mr. VOLKMER. Mr. Lemen, how do you feel about it?

Mr. LEMEN. Well, I think you have to look at how our recommendations are used. They're not only used by OSHA, but many industries in the United States and many labor unions use these in their own bargaining and for internal standards. They are also recognized throughout the world as being valid recommendations that are followed by other countries.

So while we do not get them implemented within the United States to the degree that we would like, we do feel that we are serving an important public health area by making these recommendations publicly known and providing that information to the public, so that they can use the information.

Mr. VOLKMER. You mention "recognized," and I agree with that statement. I won't disagree with the position that you serve a very necessary purpose. There is no question about that.

However, you do mention the fact that your findings, recommendations, et cetera, are also recognized in other parts of the world, et cetera, but from my study of this problem, I find that other parts of the world, especially in Europe, the problem is more recognized than in this country. Do you agree with that?

What I'm saying is that the problem is not of neurotoxins but of effects in the workplace, et cetera.

Mr. LEMEN. Well, I think that certainly there is a very valid program going on in many of the European countries, and that they do take a leadership role in occupational safety and health, simply because they've had programs ongoing legislatively for a much longer period of time than we have in the United States, but I think Dr. Baker may have a little bit more to add to that.

Dr. BAKER. I think it's true that some of the European countries have more established systems of dealing with these problems. In part, it relates to their social structure and the way they arrive at decisions and consensus on difficult issues like these. And they do not have a process like we have that is as convoluted as it is and also subject to some of the perturbations that Mr. Tyson was referring to earlier. They can deal with these things more expeditiously.

In that—in the area of neurotoxins, certainly a lot more research has been done in certain parts of Europe, and, therefore, regulations and approach to standard setting has followed accordingly.

There are some European countries that are behind us. It's a varied picture, depending on which country you're talking about.

Mr. VOLKMER. I want to thank all of you for appearing here today, and we'll still have Mr. Tyson and Dr. Baker at our next panel. This will conclude this panel. I want to thank Mr. Gough

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and Mr. Kronebusch for information and assistance herein. With that, we'll conclude this panel and we'll start with the final panel concerning hazard communication and workplace monitoring.

We'll have Mr. Tyson along with Dr. Baker, as well as Mr. Steve Sides, Director of Health Affairs, and Mr. Andrew Doyle, counsel of the National Paint and Coatings Association; and also Mr. Rod Wolford, International Brotherhood of Painters and Allied Trades.

Be seated so we can proceed.

We'll begin with Mr. Tyson on this panel. And I understand that you have to leave by quarter to one.

Mr. TYSON. If at all possible, yes, sir.

Mr. VOLKMER. You will. [Laughter.]

If we don't finish, you go right ahead and leave. I want that understood, but I think we'll be finished by then.

STATEMENT OF PATRICK R. TYSON, ACTING ASSISTANT SECRETARY, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, U.S. DEPARTMENT OF LABOR, WASHINGTON, DC

Mr. TYSON. OK. Thank you, sir. I appreciate the consideration.

How about in the interest of time I just submit my record—I mean my testimony for the record and I won't have to go through some——

Mr. VOLKMER. If you have any statements you want to summarize in regard to the communication problem and monitoring—we touched on it a little bit in a previous panel, but if you wish to make any further comments briefly at this time, that would be fine.

Mr. TYSON. I've got a summary statement, but it's about five or six pages long. It's a great piece of work, but——

Mr. VOLKMER. Go ahead. You've got time.

Mr. TYSON. OK. Let me—I'll try to read it as quickly as I can.

Mr. VOLKMER. I'll give you about 5 minutes.

Mr. TYSON. All right. Run a stopwatch on me.

OK. Let me talk now about the OSHA—OSHA has a communication standard. On November 25, 1983, OSHA promulgated its Hazard Communication Standard. This marked the culmination of nearly 10 years of rulemaking activity on a controversial and a complex issue of giving employees right to know the identities and hazards of substances that they are exposed to during the course of their employment.

OSHA believes, and the rulemaking record supports, that when employers have information about the chemicals in the workplace they are better able to devise and implement proper protective measures for their exposed employees. When employees have such information, they are better able to support and participate in such programs as well as take steps to protect themselves. This rule should result in the reduction of the occurrence of illnesses and injuries in the chemical—from chemical sources among those employees covered by this rule.

The Hazard Communication Standard represents a unique approach to regulating occupational safety and health. The Agency's rulemaking experience to date has shown that the process OSHA must follow to promulgate a standard is a lengthy and complicated

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one, as we talked about earlier today obviously, and it can be expected that few substance-specific rules will be adopted relative to the number of chemicals in the workplace. The agency has determined that requiring information on hazards and associated protective measures, and, additionally, requiring that this information be transmitted to employees and downstream employers, will provide protection for workers exposed to the many thousands of chemicals for which there is no substance-specific standard at this time. This generic approach to rulemaking will result in 14 million workers exposed to as many as 575,000 chemical products in the manufacturing-industrial sector being given information regarding the identities, hazardous properties, and precautions for safe handling and use of these products.

The basic premise of the rule is that the employers who produce or distribute hazardous chemicals are in the best position to evaluate those hazards and generate the appropriate information. Chemical manufacturers and importers are required to evaluate the hazard of the chemicals they produce or import. Chemical manufacturers, importers, and distributors are then required to insure that the containers of hazardous chemicals are labeled with appropriate information when they leave the supplier's workplaces and that material safety data sheets are provided to manufacturers who purchase these chemicals. Any employer in the industry will be thus receiving containers that are labeled as to the identity of the material, along with appropriate hazard warnings and the name and the address of the supplier or responsible party.

Employers who are manufacturers will also be receiving further detailed information through the transmittal of material safety data sheets regarding the physical and chemical characteristics of the material, its hazardous effects, and control measures. In addition to these written materials, all employers in the manufacturing sector are required to prepare and implement a hazard communication program to train employees regarding the hazards of the chemicals they are exposed to and the means to protect themselves. This comprehensive approach to communicating hazards should insure that employees both have and understand the information they need regarding the substances in their work areas.

All employees will have access to information on the labels on containers in their workplaces. OSHA chose to have additional coverage of workers in the manufacturing sector because, according to the Bureau of Labor Statistics, more than half the reported injuries and illnesses from chemical sources occur in the manufacturing sector, although this sector accounts for only about 30 percent of total employment. Since the underlying purpose of the rule is to reduce the incidence of chemical source illnesses and injuries, it appeared that the standard should be focused on the sector where they were occurring with the greatest frequency.

Following a decision by the Third Circuit U.S. Court of Appeals, OSHA will reopen the rulemaking record to expand coverage to employees in the nonmanufacturing industries unless the agency finds that such expansion is not feasible.

OSHA plans to publish an advance notice of proposed rulemaking, which I will do in about 30 days, to collect information on the current extent of hazard communication programs in industries

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other than manufacturing and the feasibility of extending to those sectors the provisions as currently written.

I think it's fair to say that there have been more —there has been more public interest in this standard than any other standard ever promulgated by OSHA. During the 2-year phase-in period for compliance that will soon be completed—and the phase-in date's November 25 for when the chemical manufacturers have to implement the standard (it is implemented in the rest of manufacturing on May 25 of next year)—during this phase-in period, OSHA has had numerous inquiries from employers and employees concerning the requirements of the standard and has devoted considerable staff resources to assisting the affected employers to come into compliance.

The agency is currently in the process of developing a special emphasis program to be implemented between November 25 and May 25 to insure that suppliers are being provided with the required information and they are providing that information to their downstream customers. We've also conducted intensive training for our compliance staff to prepare them to enforce this standard. With regard to this specific subject of this hearing, neurotoxins, it can be expected that the hazard communication standard will result in significant additional information being available to employees and employers regarding neurotoxic effects.

As I have stated previously, it's our contention that, supported by the evidence in the record, this kind of information will result in—can result and it will result in—a reduction in the occurrence of such health effects by insuring that appropriate protective measures are identified and implemented.

Although the standard is currently drawing focus on the manufacturing sector, information on labels will be available throughout industry, all industries, so that employees in nonmanufacturing will benefit as well. Since material safety data sheets have to be generated in manufacturing, it is expected that they, too, will become more readily available in sectors other than manufacturing, and employees there will benefit as well.

Moreover, the Access to Employee Exposure in Medical Records regulation, which is currently into effect and has been for a number of years, covers all workers exposed to hazardous chemicals—employees outside the manufacturing sector as well as inside. All of these employees already have access to the records of their employers giving information about chemical hazards. In other words, under Access—under the Access Standard, OSHA considers a material safety data sheet as a record of exposure if there is no other record available. So employees in areas other than manufacturing, if such a thing exists, even today have access guaranteed by OSHA to that information.

Employee exposure to toxic and physical agents is routinely assessed during OSHA inspections. Consequently, worker exposure to neurotoxins is evaluated whenever a potential exposure is recognized in the workplace. OSHA compliance officers use a variety of techniques in conducting inspections. Among other things, they interview employees, review employer safety and health programs, and analyze existing medical and exposure monitoring results.

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When there's a possibility of excessive airborne exposure to chemicals, air sampling is conducted.

When problems are found, employers are required to implement all feasible engineering controls and administrative controls to reduce contaminants to safe levels. Respiratory protection and medical surveillance programs, which measure biological indices under various standards such as lead and arsenic—and lead is a neurotoxin—are generally an integral part of the employer's protection program. In many cases respiratory protection is only permitted while other permanent control measures are being installed.

The Hazard Communication Standard has not yet gone into effect. As I've mentioned several times, it goes into effect quite soon. Program activity will be carefully monitored once it's implemented. Under development is a special emphasis program for enforcement of the standard. Compliance officers will make a special effort to ensure that the employers comply with the provisions of the standard as they go into effect.

I think it's important that early on in the process we make our presence known and our overseeing authority known to insure that the material safety data sheets are adequately prepared and that there are adequate hazard communication programs in these workplaces.

Mr. Chairman, that concludes my statement. I didn't have a stopwatch on, but I think I may have made it within five.

Mr. VOLKMER. You did fine. You did fine.

Mr. TYSON. Thank you, sir.

[Material referred to follows:]

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DRAFT

Material Safety Data Sheet
May be used to comply with OSHA's Hazard Communication Standard, 29 CFR 1910.1200. Standard must be consulted for specific requirements.

U.S. Department of Labor
Occupational Safety and Health Administration
(Non-Mandatory Form)

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable, or no information is available, the space must be marked to indicate that.

Section I

Manufacturer's Name	Emergency Telephone Number
Address (Number, Street, City, State, and ZIP Code)	Telephone Number for Information
	Date Prepared
	Signature of Preparer (optional)

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)

Section III — Physical/Chemical Characteristics

Boiling Point		Specific Gravity (H_2O = 1)	
Vapor Pressure (mm Hg.)		Melting Point	
Vapor Density (AIR = 1)		Evaporation Rate (Butyl Acetate = 1)	

Solubility in Water

Appearance and Odor

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL

Extinguishing Media

Special Fire Fighting Procedures

Unusual Fire and Explosion Hazards

(Reproduce locally)

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Section V — Reactivity Data

Stability: Unstable / Stable — Conditions to Avoid

Incompatibility (Materials to Avoid)

Hazardous Decomposition or Byproducts

Hazardous Polymerization: May Occur / Will Not Occur — Conditions to Avoid

Section VI — Health Hazard Data

Routes of Entry: Inhalation? Skin? Ingestion?

Health Hazards (Acute and Chronic)

Carcinogenicity: NTP? IARC Monographs? OSHA Regulated?

Signs and Symptoms of Exposure

Medical Conditions Generally Aggravated by Exposure

Emergency and First Aid Procedures

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled

Waste Disposal Method

Precautions to Be Taken in Handling and Storing

Other Precautions

Section VIII — Control Measures

Respiratory Protection (Specify Type)

Ventilation: Local Exhaust / Mechanical (General) / Special / Other

Protective Gloves — Eye Protection

Other Protective Clothing or Equipment

Work/Hygienic Practices

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UNION CARBIDE

MATERIAL SAFETY DATA SHEET

Union Carbide Corporation requests Customer to study this Material Safety Data Sheet and become aware of Product hazards. To promote safe handling Customer should (1) notify its employees, agents and contractors of the information on this Material Safety Data Sheet, and any Product hazards and safety information, (2) furnish a copy of this Material Safety Data Sheet to each of its customers for the Product and (3) request such customers to notify their employees and customers for the Product of the information on this Material Safety Data Sheet and any Product hazards and safety information.

PRODUCT IDENTIFICATION

PRODUCT NAME:	Ethylene Oxide		
CHEMICAL NAME:	Ethylene Oxide	CHEMICAL FAMILY:	Oxides
FORMULA:	CH_2CH_2O	MOLECULAR WEIGHT:	44.05
SYNONYMS:	1,2-Epoxyethane; Oxirane		
DEPARTMENT OF TRANSPORTATION	HAZARD CLASSIFICATION	Flammable Liquid	
	SHIPPING NAME	Ethylene Oxide	
CAS # 75-21-8	CAS NAME Oxirane		

PHYSICAL DATA

BOILING POINT, 760 mm. Hg	10.4 °C (50.7 °F)	FREEZING POINT	−112.6 °C
SPECIFIC GRAVITY (H_2O = 1)	0.8711 at 20/20 °C	VAPOR PRESSURE at 20 °C	1,095 mm Hg
VAPOR DENSITY (air = 1)	1.49	SOLUBILITY IN WATER, % by wt.	Complete
PER CENT VOLATILES BY VOLUME	100	EVAPORATION RATE (Butyl Acetate = 1)	72
APPEARANCE AND ODOR	Shipped and stored under nitrogen pressure as a liquid. Colorless gas, nonresidual odor.		

HAZARDOUS INGREDIENTS

MATERIAL	%	TLV (Units)	HAZARD
Ethylene Oxide	100	5 ppm, ACGIH, 1981	Irritant
		Notice of Intended Changes	Toxic
		50 ppm, OSHA, CFR 29	Suspect Cancer Agent
		Para. 1910. 1000 Table Z-1	Flammable
		5 ppm, UCC Internal	

FIRE AND EXPLOSION HAZARD DATA

FLASH POINT [test methods]	< 0 °F, Tag Closed Cup ASTM D 56. < 0 °F, Tag Open Cup ASTM D 1310.				
FLAMMABLE LIMITS IN AIR, % by volume		LOWER	3	UPPER	100

EXTINGUISHING MEDIA	Use water spray, carbon dioxide, dry chemical, alcohol-type or universal-type foams applied by manufacturers' recommended technique.
SPECIAL FIRE FIGHTING PROCEDURES	During large releases of ethylene oxide, shut off supply of fuel. It may be best to allow fuel to burn out and to protect adjacent surfaces with application of water. Dilution of ethylene oxide with 100 volumes of water renders it nonflammable.
UNUSUAL FIRE AND EXPLOSION HAZARDS	The vapors of ethylene oxide will burn without presence of air or additional oxidizer. Ethylene oxide under certain conditions will decompose explosively.

F-49167 EFFECTIVE DATE: JUNE 1, 1982

EMERGENCY TELEPHONE NUMBER

304/744-3487

This number is available days, nights, weekends, and holidays.

UNION CARBIDE CORPORATION • ETHYLENE OXIDE/GLYCOL DIVISION
OLD RIDGEBURY ROAD, DANBURY, CT 06817

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HEALTH HAZARD DATA

TLV AND SOURCE	5 ppm–ACGIH (1981 Notice of Intended Changes) 50 ppm–OSHA, CFR 29 Para. 1910.1000, Table Z-1

ACUTE EFFECTS OF OVEREXPOSURE	
SWALLOWING	A very unlikely route of exposure. Severe irritation and ulceration of the mouth and throat, abdominal pain, nausea, vomiting, collapse, and coma.
SKIN ABSORPTION	Sustained contact with the skin is unlikely, but could lead to headache, dizziness, nausea, and vomiting.
INHALATION	Irritation of the eye, nose, and throat. Headache, nausea, vomiting, diarrhea, coughing, chest tightness, cyanosis, weakness, drowsiness, loss of coordination, convulsions, and coma. Delayed onset pulmonary edema may occur.
SKIN CONTACT	With liquid, delayed onset of erythema, edema, vesiculation, and blister formation. Usually several hours to onset.
EYE CONTACT	Burns from liquid, moderate eye irritation from vapor.
CHRONIC EFFECTS OF OVEREXPOSURE	Ethylene oxide is mutagenic. Animals exposed to ethylene oxide vapor for up to 2 years have shown an increase in the incidence of malignant tumors compared with controls. Ethylene oxide should be regarded as a suspect cancer agent.
OTHER HEALTH HAZARDS	Allergic contact dermatitis may occur. A few cases of neuropathy (mainly peripheral) have been described from recurrent exposure to high vapor concentrations.

EMERGENCY AND FIRST AID PROCEDURES	
SWALLOWING	Drink a glass of water and induce vomiting. Call a physician.
SKIN	Immediately remove contaminated clothing and wash skin copiously with soap and water.
INHALATION	Remove to fresh air, and administer oxygen if breathing is difficult. Observe for vomiting. If breathing stops, start artificial respiration.
EYES	Flush immediately with water and continue for at least 15 minutes. The advice of an ophthalmologist should be sought urgently.

NOTES TO PHYSICIAN

1. Persons exposed to ethylene oxide may develop severe and intractable vomiting, requiring the use of antiemetics given intravenously.
2. Prolonged or high vapor concentration exposure may result in the development of pulmonary edema after a latent phase of several hours. Also, respiratory tract injury caused by ethylene oxide may predispose to the development of a secondary respiratory infection. Individuals exposed to moderately high vapor concentrations of ethylene oxide should be retained for observation.
3. Following skin contamination, primary irritation and blister formation may be delayed in onset.

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VI. REACTIVITY DATA

STABILITY		CONDITIONS TO AVOID	Stable at ordinary conditions of temperature and pressure, and in ordinary use, handling, and storage; however, will decompose violently at temperatures above 800 °F.
UNSTABLE	STABLE		
—	√		

INCOMPATIBILITY (materials to avoid)	Alkalies and acids.
HAZARDOUS COMBUSTION OR DECOMPOSITION PRODUCTS	Burning can produce carbon monoxide and/or carbon dioxide.

HAZARDOUS POLYMERIZATION		CONDITIONS TO AVOID	Will not polymerize spontaneously under conditions of temperature, pressure, etc. However, will polymerize violently if contaminated with aqueous alkalies, amines, mineral acids, metal chlorides, or metal oxides.
May Occur	Will not Occur		
√	—		

VII. SPILL OR LEAK PROCEDURES

STEPS TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED	Eliminate all sources of ignition. Wear suitable protective equipment. (See Section IX.) Flood the spill with water spray. Contain the spilled material and collect it for disposal.
WASTE DISPOSAL METHOD	Incinerate in a furnace where permitted under Federal, State, and local regulations. (See Section IX.)

VIII. SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION (specify type)	Self contained breathing apparatus in high concentrations.		
VENTILATION	This product must be confined with in vapor tight equipment and stored under pressurized nitrogen or other suitable inert gas. Confined in this manner, vapors should not be released and general (mechanical) room ventilation is expected to be satisfactory.		
PROTECTIVE GLOVES	Gloves are not recommended during sampling	EYE PROTECTION	Monogoggles
OTHER PROTECTIVE EQUIPMENT	Eye bath, Safety shower		

IX. SPECIAL PRECAUTIONS

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING

Keep away from heat, sparks, and open flame.
Do not get in eyes, on skin, or on clothing.
Do not breathe vapor.
Keep container closed.
Use with adequate ventilation.
Wash thoroughly after handling.
Ground all lines.

FOR INDUSTRY USE ONLY

OTHER PRECAUTIONS: Ethylene oxide is highly toxic to most forms of life and is considered a potential environmental pollutant. Indiscriminate dumping into sewers or waterways must be avoided. Incineration is the preferred method of disposal. In aqueous solution, it may be feasible to convert to ethylene glycol and dispose of glycol solution.

Biological Treatment: Ethylene oxide is amenable to disposal in standard bacteriological waste treatment facilities under controlled conditions after proper acclimation of system.

Protection Equipment: Use monogoggles when handling ethylene oxide. Have air supplied mask available for use if high vapor concentrations exist. Safety showers and eye baths must be available.

In case of spillage: remove all contaminated clothing. All leather articles, such as shoes, and gloves, must be discarded because ethylene oxide may be retained in them and is very difficult to remove even by washing.

For emergency conditions, a self-contained breathing air apparatus should be available. When emergency work must be done in vapor, fresh air masks and rubber suits with inside air purge provisions should be used.

The ... use of purchased ... within Union ... to Corporation. We believe that the ... contained herein ... current ... to the date of this ... Safety Data Sheet. Since the ... mation and their ... and the ... use of the prod... are not ... the ... of ... vehicle. Under ... is the user's ... to determine ... conditions of ... use of the product.

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UNION CARBIDE CORPORATION
UNION CARBIDE
ETHYLENE OXIDE
DANGER! EXTREMELY FLAMMABLE.
HARMFUL IF INHALED.
CAUSES EYE AND SKIN BURNS.
SUSPECT CANCER HAZARD.
Keep away from heat, sparks, and open flame.
Do not breathe vapor.
Do not get in eyes, on skin, on clothing.
Keep container closed.
Use with adequate ventilation.
Wash thoroughly after handling.
FIRST AID: If inhaled, remove to fresh air, if not breathing, give artificial respiration. If breathing is difficult give oxygen. Call a physician.
In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Call a physician. Wash clothing before re-use.
DOT I.D. NUMBER UN 1040
FOR ADDITIONAL SAFETY INFORMATION, SEE CURRENT UNION CARBIDE MATERIAL SAFETY DATA SHEET F-43133.
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Mr. VOLKMER. Mr. Sides?

STATEMENT OF STEVE SIDES, DIRECTOR OF HEALTH AFFAIRS, NATIONAL PAINT & COATINGS ASSOCIATION, WASHINGTON, DC

Mr. SIDES. Thank you, Mr. Chairman.

My name is Steve Sides. I'm a certified industrial hygienist and manager of health affairs for the National Paint and Coatings Association.

We provided a written statement to the committee, and my remarks today will summarize those.

I'm pleased to be with you to discuss the issue of workplace hazard communication. And with me is Andy Doyle, NPCA legal counsel.

The National Paint and Coatings Association is a voluntary, nonprofit industry association comprising over 800 members. The membership of NPCA collectively produces over 90 percent of the total national volume of paint and allied products. Our membership manufactures products for use at both the industrial and consumer level.

Thus, the industry is quite concerned with insuring that its customers and employees are provided with appropriate hazard information.

Today my comments will focus on the following areas: The paint industry's approach to health and safety and the paint industry's views in the Occupational Safety and Health Administration's hazard communication standard.

Let me turn to our industry's health and safety program. The paint industry has for many years been in the forefront of commu-

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nicating the potential hazards of its products to its employees, its customers, and the consuming public.

To help achieve meaningful results, NPCA has developed two tools to assist in communicating those hazards: the Paint Industry Labeling Guide and the Hazardous Materials Identification System. The primary objective of each of these tools is to better inform the user of the industry's products both as to the potential hazard and the proper handling and use.

Back in 1962 NPCA developed a program for labeling containers with appropriate hazard information. We continue today to advise our members as to appropriate labeling guidance through the publication of the Paint Industry Labeling Guide. The guide is an ever-evolving manual. It is continually updated and reflects current State and Federal requirements and state-of-the-art labeling in the paint and coatings industry.

The labeling recommendations set forth in the guide are based upon current science and deal with both chronic and acute health hazards.

In the same spirit as this labeling guide, in 1978 NPCA developed the Hazardous Materials Identification System or HMIS. We've provided the committee with a number of examples of HMIS materials, and I'll be referring to those through the balance of my talk.

The HMIS is a comprehensive hazard communication system designed for use throughout the paint and coatings industry. Although the system was developed primarily for use within the paint manufacturing industry, it is easily adaptable to other industries. In fact, NPCA's HMIS has been accepted as a means of compliance with the OSHA hazard communication standard.

The HMIS uses a numbering system ranging from zero to 4 to alert employees of the potential hazards associated with the products they're working with. One of the primary vehicles of communication is the HMIS label. Instead of using words and phrases, as is traditional with consumer product labels, the HMIS label uses numbers and colors to describe the relative hazards of the products.

I would like to refer to the label. It's a four-colored square that describes the health, flammability, and reactivity hazards of a particular material, as well as the appropriate personal protective equipment to be worn. Each of the categories—health, flammability, and reactivity—are then assigned a rating from zero, representing a minimal hazard, to 4, representing a severe hazard, based on the relative hazards of that chemical.

In the case of personal protective equipment, a letter designation is provided that refers an employee to a chart such as the one you see on the easel here or a wallet card, which we've provided you as an example.

[The sample follows:]

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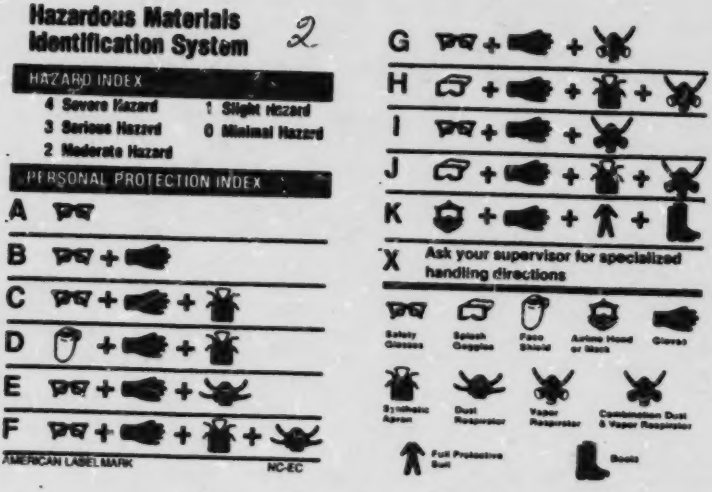
Latex Acrylic



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Mr. SIDES. These pieces of information describe the appropriate personal protective equipment to be worn in a particular situation. Of course, the type of protective equipment recommended on the wallet card not only reflects normal conditions of use, but it is also reflective of whether the employee is coming in direct contact with the chemical, what route of exposure he might be anticipated to have, and what type of conditions may be encountered during spills or other emergency situations.

On the label itself, the health hazard is represented by a blue field; the flammability hazard, by a red field; the reactivity hazard, by a yellow field; and the personal protective equipment, by a white field.

For example, on a typical label, which we have here for the Latex Acrylic Emulsion, the health rating would be zero; the flammability rating would be zero; the reactivity rating would be zero; and the personal protection rating would be "B," designating gloves and safety glasses should be worn.

Mr. SIDES. In order for the manufacturer to be able to assign these HMIS hazard ratings, he must first go through a hazard assessment. This is a process by which potential hazards are discovered and defined.

In the case of paint and coatings industry, the hazard assessment process does not develop from basic chemical research but from information provided by industries which supply raw materials. This information is provided primarily in the form of material safety data sheets, which have become the most common mechanism for hazard communication.

Under our HMIS, the employer will establish a chemical identity for each of the hazardous materials used in the manufacturing facility. According to OSHA, chemical identity means any chemical or common name, including code numbers, trade names, or brandnames, which appear on the material safety data sheet and on the label. This identity is then used to link the label and the MSDS for hazard communication.

The employer will then determine the key to HMIS; that is, the HMIS rating for each material. The rating is established according to well-defined criteria used to determine the acute health, flammability, and reactivity hazards. We've provided you with a copy of the specific criteria for each of those categories.

This criteria, as well as the information provided on the material safety data sheet by the chemical supplier, is then combined to develop the numerical hazard rating from zero to four.

The final portion of the hazard assessment involves the determination of chronic or long-term health hazards. These hazards are not considered when assigning an acute health rating because of complex issues involving classifications and tests. In this situation the paint manufacturer must rely on the supplier's material safety data sheet to properly identify the chronic hazards which must be communicated.

The HMIS is a very comprehensive hazard communication system. The primary reason for developing this type of system was to provide the paint manufacturing employee with an effective, easily identifiable hazard warning system. It also should be noted that HMIS is not dependent on complicated descriptive warnings

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and is not intended to replace the traditional forms of label warnings presently used on consumer products.

NPCA believes that, to best warn consumers of potential hazards associated with the use of our products, it is essential to continue to use the type of recommendations that are set forth in our labeling guide and which are consistent with the requirements of the Federal Hazardous Substance Act.

Let me now mention two other programs that the industry has implemented to better protect users of its products.

First, in April 1982 NPCA published a Guide to Respirator Fit Testing. This guide is designed to assist employers in complying with the fit test provisions of OSHA's respiratory protection standard. At the same time, we believe that this improved compliance will better insure that the industry's employees are using effective respiratory protection. In fact, NIOSH is using the manual in their current training program for respirator protection.

The second program I'd like to point out is that we're—is one we're just embarking on. In July of this year our executive committee approved the establishment of a national public education program. The primary objective of this program is to better educate the consumer and professional painter on how to use paint and coatings properly.

For example, NPCA plans video presentations that would better inform consumers about how to use products safely and, above all, urge them to read and heed the labels. We are very excited and proud of this program and believe it can go a long way to reducing the International Brotherhood of Painters and Allied Trades in joint programs addressing hazard communication.

The Brotherhood has commented on HMIS, which I've just described, and is currently working with us on a joint respirator fit test training program which will be jointly administered. We encourage this effort and will continue to do so, particularly in getting their input on our ongoing public education program.

Now at this time I'd like to address our involvement and our views on the OSHA hazard communication standard. NPCA has long supported OSHA's development of the Federal hazard communication standard. Initial involvement in this OSHA project began in 1974 when an NPCA delegate served on OSHA's Standards Advisory Committee on Hazardous Materials Labeling.

The work of this committee laid the foundation for the standard recently adopted by OSHA. Also, NPCA has filed written comments and given testimony at every stage of the rulemaking process of the final standard.

During the OSHA rulemaking proceedings NPCA vigorously endorsed the need for a uniform national hazard communication standard. NPCA also addressed the broad range of substantive issues raised by the proposed standard, including the scope of the standard, the requirements for labeling containers, the sorts of information which should be listed on the material safety data sheets, the components of an effective employee information and training program, and the need for preemption of State right-to-know laws to thus insure uniformity and effective enforcement.

NPCA supports the philosophy behind and the requirements of the OSHA standard. NPCA also encourages OSHA to go beyond

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those requirements by expanding the scope of the standard to include employers outside the manufacturing standard industrial classifications of 20 through 39.

While we recognize that this expansion can be a complicated process for some industries, we believe that in order for the standard to be as effective as possible, this expansion must be done.

As the scope of the OSHA hazard communication standard is expanded to include other industry categories, NPCA looks forward to working with OSHA to insure that the HMIS system will continue to be accepted as a means of compliance.

In conclusion, let me stress that the paint industry is committed to the development of health and safety programs that insure the continued safe use of our products. It is in the best interest of all concerned—our employees, the consuming public, and industry—that we act responsibly in the area of hazard communication. As a result, the paint industry stands willing to support programs that minimize employee risks.

We appreciate the opportunity to be here with you today and stand ready to answer any questions you may have.

[The prepared statement of Mr. Sides follows:]

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STATEMENT OF THE

NATIONAL PAINT AND COATINGS ASSOCIATION, INC.

BEFORE THE

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

OF THE

COMMITTEE ON SCIENCE AND TECHNOLOGY

Good morning Mr. Chairman and members of the Subcommittee. My name is Steve Sides, Manager of Health Affairs for the National Paint and Coatings Association (NPCA). I am pleased to be with you today to discuss the issue of workplace hazard communication. With me today is Andy Doyle, NPCA legal counsel.

NPCA is a voluntary, non-profit industry association comprising over 800 members. The membership of NPCA collectively produces over 90 percent of the total national volume of paint and allied products. Our membership manufactures products for use at both the industrial and consumer level. Thus, the industry is quite concerned with ensuring that appropriate information regarding the potential health effects associated with the use of paints and coatings is disseminated to the users of such products.

Today, my comments will focus on the following areas:

--The paint industry's approach to health and safety; and

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--The paint industry's views on the Occupational Safety and Health Administration's Hazard Communication Standard.

I. THE PAINT INDUSTRY'S APPROACH TO HEALTH AND SAFETY

The paint and coatings industry has, for many years, been in the forefront of communicating the potential hazards of its' products to its' employees, its' customers, and the consuming public. To help achieve meaningful results, NPCA developed two tools to assist in communicating those hazards: The Paint Industry Labeling Guide and The Hazardous Materials Identification System. The primary objective of each of these tools is to better inform the user of the industry's products, both as to the potential hazards and the proper handling and use.

A. PAINT INDUSTRY LABELING GUIDE

Back in 1962, NPCA developed a program for labeling containers with appropriate hazard information. We continue, today, to advise our members as to appropriate labeling guidance through the publication of The Paint Industry Labeling Guide. The Guide is an ever-evolving manual, continually updated, reflecting current State and Federal requirements and state of the art labeling in the paint and coatings industry. The labeling recommendations set forth in the Guide are based upon current science and deal with both chronic and acute health hazards.

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The Guide provides information to manufacturers of paints and coatings, and to suppliers of raw materials used in the manufacture of paints and coatings, so as to assist them in developing labels for their products which come under Federal, State and local labeling laws and regulations. To the extent feasible, we have also incorporated current trade practices in the labeling guidelines. Thus, the labels contained in the Guide are guidelines in the true sense of the word and should not be considered directives.

While the sample labels set forth in the Guide may not be applicable to every labeling law or regulation, NPCA believes that they do respond to the basic legal requirements under current laws and regulations for precautionary labeling of the known hazards usually associated with, or likely to be imparted to, the finished paint product by its ingredients. Each individual manufacturer, however, is responsible for properly labeling his finished products based on the foreseeable hazard(s) involved in their handling and use, rather than on the basis of intrinsic hazard(s) of the individual components/ingredients.

The Guide's primary purpose is to enable manufacturers of paints and coatings to provide their customers (both consumer and industrial) with fair and adequate warnings as to the known hazardous properties of their products. By this means, notice of the possible consequences during use or misuse of such products

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will be called to the users'/customers' attention.

For example, in January of this year we published labeling guidance warning of the potential dangers associated with repeated and prolonged occupational overexposure to solvents. This labeling guidance has been provided to the Consumer Product Safety Commission, the Occupational Safety and Health Administration, and the Environmental Protection Agency. In summary, the consumer label instructs users to open all windows and doors or use other means to ensure fresh air entry. It goes on to point out that if you experience any of the symptoms of overexposure, such as eyewatering, headaches or dizziness, you should increase fresh air entry, wear a respirator, or leave the area. On the industrial side, the label instructs employees to use respiratory protection unless air monitoring shows exposure levels are below applicable limits. Finally, the label incorporates a warning that deliberately concentrating the vapors may lead to permanent injury or death.

Unfortunately, the Paint Industry Labeling Guide and this type of industry initiative is fast becoming a rare resource. The tremendous increase in product liability lawsuits, including some involving trade associations as defendants, have forced such associations to abandon such innovative programs. The result is that programs which help protect users will no longer be available. NPCA sincerely hopes that its efforts in assisting its members in labeling guidance will not be sacrificed to avoid lawsuits and encourages the consideration of responsible

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Federal action to avoid such a situation.

B. HAZARDOUS MATERIALS IDENTIFICATION SYSTEM

In the same spirit of the Labeling Guide, in 1978, NPCA developed the Hazardous Materials Identification System (HMIS). The HMIS is a comprehensive hazard communication system, designed for use throughout the paint and coatings industry. Although the system was developed primarily for use within the paint manufacturing industry, it is easily adaptable to other industries. In fact, NPCA's HMIS has been accepted as a means of compliance with the OSHA Hazard Communication Standard [48 FR 53280, November 25, 1983].

Unlike the Paint Industry Labeling Guide, the HMIS uses a numbering system ranging from 0-4 to alert employees of the potential hazards associated with the products they are working with. One of the primary vehicles of communication in the HMIS is the label. Instead of using words and phrases, as is traditional with consumer product labels, the HMIS uses numbers and colors to describe the relative hazards of products. The HMIS label is a four-color square that describes the health, flammability, and reactivity hazards of a particular material as well as the appropriate personal protective equipment to be worn. Each of the hazards (health, flammability, and reactivity) are then assigned a rating from 0-4 based on the relative hazard of the chemical. In the case of personal protective equipment, a letter designation is provided that refers an employee to a chart or a wallet card which describes the appropriate personal protective

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equipment to be worn in a particular situation. The type of protective equipment recommended on the wallet card reflects not only the normal conditions of use but, in general, is also reflective of whether direct employee contact with the chemical is possible, what route of exposure is anticipated, and what type of conditions may be encountered during spills or other emergency situations. On the label itself, the health hazard is represented by a blue field, the flammability hazard by a red field, the reactivity hazard by a yellow field, and the personal protective equipment by a white field. For example, on a typical label for latex acrylic emulsion the health rating would be 0, the flammability rating would be 0, the reactivity rating would be 0, and the personal protection rating would be B, designating that gloves and safety glasses be worn.

In order for a manufacturer to be able to assign these HMIS hazard ratings illustrated above, he must first go through a hazard assessment. This is the process by which potential hazards are discovered and defined. In the case of the paint and coatings industry, the hazard assessment process does not develop from basic chemical research but from information provided by the industries which supply raw materials. This information is provided primarily in the form of Material Safety Data Sheets, which have become the most common mechanism for hazard communication.

Under our HMIS, the employer will establish a chemical identity for each of the hazardous materials used in the manufacturing facility. According to OSHA "chemical identity" means

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any chemical or common name (including code numbers, trade names or brand names) which appears on the MSDS and on the label of the material. This identity is then used to link the label and the MSDS for hazard communication.

The employer will then determine the key to HMIS: the HMIS rating of each hazardous material. This HMIS rating is established according to well defined criteria used to determine the acute health, flammability and reactivity hazards. This criteria, as well as the information provided on the MSDS by the chemical supplier is then combined to develop the numerical hazard ratings from 0 to 4.

The final portion of the hazard assessment involves the determination of chronic or long-term health hazards. These hazards are not considered when assigning an acute health rating because of complex issues involving classifications and tests. In this situation, a paint manufacturer must rely on the suppliers' MSDS to properly identify the chronic health hazards which must be communicated.

As shown above, the HMIS is a very comprehensive hazard communication system. The primary reason for developing this type of system was to provide the paint manufacturing employee with an effective, easily identifiable hazard warning system. It also should be noted that HMIS is not dependant on complicated descriptive warnings, and is not intended to replace the traditional form of label warning presently used for consumer products. NPCA believes that to best warn consumers of the potential hazards

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associated with the use of our consumer products, it is essential to continue to use the type of recommendations that are set forth in our Labeling Guide and which are consistent with the requirements of the Federal Hazardous Substances Act.

C. KEEPING HMIS CURRENT

In order to maintain the suitability of HMIS for regulatory compliance and practical application for industry users, NPCA recognizes the need for periodic revisions. To facilitate this, NPCA member companies support NPCA-sponsored seminars and technical committees to communicate and share information on implementation of HMIS.

In addition to paint industry support, the participation of the industry's suppliers is critical to the acceptance of HMIS as a hazard communication program. Chemical manufacturers who supply raw materials to the paint industry have on some occasions agreed to develop and supply HMIS ratings and labels for their customers. More often, however, the industry's suppliers will provide the paint manufacturer with detailed hazard information that he can then use to derive the hazard ratings.

Also, to facilitate the utilization of HMIS information on paint products used by the construction industry, NPCA is exploring cooperative programs with the Painting and Decorating Contractors Association and the International Brotherhood of Painters and Allied Trades. Inherent in these programs is the expansion of HMIS labeling for finished paint and coatings products as well as comprehensive training programs for contractors and

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professional painters.

Many of NPCA's efforts in hazard communication and product labeling have been initiated and promoted voluntarily and not prompted by government regulations. We believe this to be the most responsible approach. On the other hand, we believe regulatory agencies play an important role in refining and clarifying the objectives of our voluntary efforts so as to create a safe and healthful workplace.

D. RESPIRATOR FIT TEST GUIDE

Let me now turn to three other programs the industry has implemented that serve to better protect users of its products. First, in April of 1982 NPCA published a Guide to Respirator Fit Testing. This Guide is designed to assist employers in complying with the fit test provisions of the Occupational Safety and Health Administration's Respiratory Protection Standard. [29 CFR 1910.134] At the same time, we believe that this improved compliance will better ensure that the industry's employees are using the appropriate respiratory protection. The Guide is divided into six parts: an introduction describing the goals and objectives of the fit test program, initial procedures and equipment needs, scripts for the accompanying slide/tape program, information on choosing a respirator, and specific procedures for conducting the isoamyl acetate fit test and the sweetener aerosol fit test.

The primary purpose of this Guide is to encourage employers and employees to fit test respirators before use. This fit

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test is then used to determine whether a given respirator conforms to the facial features of an individual. It also assures that a person is familiar with the proper way to put on and wear a respirator. If a person passes one of the fit tests described in this Guide, the protection afforded is at least equal to or better than the OSHA limits for that model of respirator.

E. HEALTH AND SAFETY BULLETINS

Another ongoing NPCA program aimed at increasing our member company awareness of the potential health and safety hazards from paint products, is the publication of Safety and Health Bulletins. On an as needed basis, NPCA's Technical Division publishes Safety and Health Bulletins on a wide range of issues of specific interest to paint manufacturers. For example, when studies show certain new chronic or acute health effects associated with any of our products, the appropriate NPCA Task Force, such as our Occupational Health/Product Safety Task Force, will review data and conduct a hazard assessment. This data and the Task Forces' hazard assessment will then be published in a Safety and Health Bulletin and distributed to our membership. Many times this Bulletin will contain recommended actions, including labeling guidance. On other occasions it will serve as an alert to our members recommending they use this information where appropriate. These bulletins are available to government agencies and are routinely sent to OSHA, EPA and CPSC.

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F. PUBLIC EDUCATION PROGRAM

Finally, I would like to point out one more project that NPCA is currently embarking upon. Just recently, our Executive Committee approved the establishment of a National Public Education Program. The primary objective of this program is to better educate the public on how to use paint and coatings properly. For example, NPCA plans video presentations that would better inform consumers about how to use our products safety and, above all, urge them to read and heed the labels. We are very excited about and proud of this program and believe it can go a long way to reducing potential risks.

II. THE PAINT INDUSTRY'S VIEWS ON THE OSHA HAZARD COMMUNICATION STANDARD

At this time I would like to address our involvement in and our views on the OSHA Hazard Communication Standard. As you are aware, the Occupational Health and Safety Administration (OSHA) published the Hazard Communication Standard on November 25, 1983. The Standard requires chemical manufacturers (SIC Code 28) to "assess the hazards of chemicals which they produce or import, and (requires) all employers in the manufacturing division (SIC Codes 20-39) to provide information to their employees concerning hazardous chemicals [through] a formal hazard communication program." Implementation of the OSHA Hazard Communication Standard is expected to reduce the incidence of chemically related occupational illnesses and injuries in the manufacturing sector through increased awareness of workplace hazards and available

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protection mechanisms among employers and employees alike.

NPCA long has supported OSHA's development of a Federal hazard communication standard. NPCA's initial involvement in this OSHA project began in 1974 when one of the NPCA delegates served on OSHA's Standards Advisory Committee on Hazardous Materials Labeling. The work of this Committee laid the foundation for the Standard recently adopted by OSHA.

NPCA has filed written comments and given testimony at every stage of the rulemaking process on the final Standard. On March 29, 1977, NPCA filed comments in response to OSHA's Advance Notice of Proposed Rulemaking, which was published at 42 FR 5372 (January 28, 1977). Supplemental Comments were filed on December 12, 1977. On May 18, 1982, NPCA responded to the March 14, 1982 Notice of Proposed Rulemaking, 47 FR 12092, by submitting 43 pages of comments addressing approximately 15 separate issues. NPCA, on August 31, 1982, filed 38 pages of Supplemental Comments. In addition to the submission of written comments, several officials and members of NPCA presented testimony at the OSHA hearings held before Judge Levin in Washington, D. C. on June 17, 1982.

During the OSHA rulemaking proceedings, NPCA vigorously endorsed the need for a uniform National hazard communication standard. NPCA also addressed a broad range of substantive issues raised by the proposed standard, including the scope of the standard, the requirements for labeling containers, the sorts of information which should be listed on Material Safety

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Data Sheets (MSDS), the components of an effective employee information and training program, and the need for preemption of state right-to-know laws to ensure uniformity and effective enforcement.

Further, NPCA participated as a Respondent Intervenor in the challenge to the OSHA Standard, United Steelworkers of America v. Auchter, United States Court of Appeals for the Third circuit. In joining that action, NPCA sought to uphold the OSHA Standard as a viable means to better protect employees from workplace hazards. NPCA supports the philosophy behind and the requirements of the OSHA Standard. NPCA also encourages OSHA to go beyond those requirements by expanding the scope of the Standard to include employers outside manufacturing SIC Codes 20-39. While we recognize that this expansion can be a complicated process for some industries, we believe that in order for the Standard to be as effective as possible this expansion must be done. As the scope of the OSHA Hazard Communication Standard is expanded to include other industry categories, NPCA looks forward to working with OSHA to ensure that the HMIS system will continue to be accepted as a means of compliance.

IV. CONCLUSION

In conclusion, let me stress that the paint industry is committed to the development of health and safety programs that ensure the continued safe use of our products. It is in the best interests of all concerned, our employees, the consuming

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public and industry, that we act responsibly in the area of hazard communication. As a result, the paint industry stands willing to support programs that minimize employee risks. We appreciate the opportunity to be here with you today and stand ready to answer any questions you may have.

Respectfully submitted,

LS/ LS/

Stephen R. Sides, Manager Health Affairs

J. Andrew Doyle, Counsel

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Mr. VOLKMER. Thank you very much.
Mr. Wolford.

STATEMENT OF RODNEY D. WOLFORD, DIRECTOR, DEPARTMENT OF HEALTH AND SAFETY, INTERNATIONAL BROTHERHOOD OF PAINTERS & ALLIED TRADES

Mr. WOLFORD. Yes. Thank you for having me here.

My name is Rodney Wolford, health and safety director for the 180,000-member International Brotherhood of Painters & Allied Trades. For the past 9 years I have researched, written, and produced training materials for our union's members. In that time I and my colleague, Marilyn Larson, have prepared a 272-page text and quiz book and 48 videotapes for training paint and allied trade workers in hazard recognition and control methods.

Our materials are now used by 125 field instructors and have been used to deliver 300,000 hours of training to 25,000 members during the past seven years. Much of our work has focused on painters.

Each year 450,000 painters use about 8.6 billion pounds of coatings. In this paint are 150 known or suspected carcinogens and a greater number of workplace neurotoxins and other physically and biologically active substances capable of killing or maiming workers.

Used properly, the risk posed by these products can be minimized. No exposure, no harm; if no harm, then no risk. Unfortunately, there appears to be plenty of harm—plenty of exposure and a commensurate harm.

Painters often work without fans or respirators in areas with solvent concentrations reaching 10 to 200 times the OSHA permissible exposure limits. Sometimes buildings explode. Sometimes workers

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are overcome by fumes or asphyxiated. These events you may read about in the newspaper or see on TV.

But accidents and sudden death are rare events and the human being is a remarkable machine. So most painters just come and go in these hazardous work environments day after day, often feeling nauseous, dizzy, fatigued, headachey, or sick. In fact, Dr. Irving Selikoff in this 1975 Investigations of Health Hazards in the Painting Trades found 74 percent of all painters experienced neurotoxic effects. For some, this process of overexposure is repeated week after week, month after month, and year after year.

Often our contact with such members begins when an acute exposure temporarily incapacitates or hospitalizes the painter. They report accelerated loss of energy, vitality, screaming at children or spouses, uncontrolled rage without provocation, vague complaints of ill health, kidneys that hurt, they can't sleep, experience sexual dysfunction. Sometimes they black out while driving home from work. At night their breath smells like today's paint, and the next morning their urine smells the same. They can't remember names and dates, where they've been or what they went to the store to buy. Mostly, they stop caring, stop feeling, and stop living, and many remark that they just wish they were dead.

Not all of our evidence is anecdotal. Several hundred scientific papers demonstrate statistically significant relationships between solvent-exposed occupations and disease and illnesses such as neurotoxin-induced dementia.

In one Swedish study involving painters, a toxic encephalopathy nicknamed "Chronic Painter's Syndrome" was identified among house painters. Clinical signs included brain size atrophy; that is, the size of the brain actually shrunk in the painters exposed.

I'm sure most would agree that pain and suffering among victims of workplace neurotoxins is unjustifiable when feasible means of exposure control are not implemented. Two such means of exposure control are those this subcommittee has asked me here to address today: hazard communication and workplace monitoring.

You also have requested our comments on effective hazard training programs—the effectiveness of hazard training programs on reducing worker exposure to neurotoxins and the use of low-cost technologies for monitoring workplace exposures.

The destruction of human minds and nervous systems by workplace chemicals is not some story made up by workers to escape from their jobs or to perpetuate fraud against manufacturers, social security, welfare agencies, or the U.S. public. The anecdotal and epidemiological work tells us that.

And delaying regulatory or voluntary action while searching for so-called individual bad actor chemicals is not likely to move us any closer to minimizing the risk of those now exposed. The dismal record of substance-by-substance regulation of carcinogens tells us also that.

We have a chance here to significantly reduce chemical exposures for a wide variety of workers just by accepting that neurotoxins may cause temporary or permanent impairment or harm and do pose a significant risk which must be controlled by assuring that no worker is exposed in doses or for durations that cause signs or symptoms of overexposure to be manifested.

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Accepting that responsibility, the neurotoxin control can play a significant part in reducing worker risks from other disease-causing agents. In other words, neurotoxic symptoms may also serve as a valuable sign of general overexposure to a product.

Currently, IBPAT is analyzing workplace behavior and attendance, self-reported and clinical health status change among painters with an emphasis on neurological signs and symptoms. This evaluation which was designed by Marilyn Larson, who is the study's principal investigator, and me has been made possible by a National Cancer Institute Research grant to our union for assessing effectiveness of our training materials in reducing cancer risk. I think our study illustrates the power of using neurotoxic symptoms as a control indicator for worker exposures. Here's how it works:

Preimposed training, we compare with and between trained and nontrained painter groups the frequency of use of fans and respirators and the frequency of cleaning hands and face with solvents and the prevalence of neurotoxic signs and symptoms. If the training works—that is, if use of fans and respirators goes up, the cleaning of skin with solvents goes down, and the neurotoxic signs and symptoms of overexposure correspondingly reduce in the trained group but remain unchanged in the nontrained group—then we can conclude that the training had measurable effects on behavior and health outcomes associated with lower exposures; hence, reducing their risk.

Now because many neurotoxins are or are found together with carcinogens in paint products, this risk reduction associated with short-term effects of solvent overexposure may serve as a proxy for lowering risk of long-term diseases, including cancers.

If no corresponding change in behavior or symptoms are found, then either the training doesn't work or its effect cannot be measured by the parameters we've designed, and the effectiveness of the training remains unknown.

Such an assessment represents the bottom line in using communications such as training or labeling as a means of reducing worker exposures. Does the training or the label perform? Does it communicate its message? Does the message measurably change behavior? Do the measurable behavioral changes produce correspondent measurable reductions in exposure? That is, does the training or the label actually reduce risk or is it just a Machiavellian exercise to meet the statutory obligations, reduce corporate liability, and make undeserved profits from exploiting worker health to the long-term detriment of the public, future generations, and the overall well-being of our country?

Of course, the answer to these questions cover an area of hazard communication far broader than the issues of neurotoxins. Hazard communication is more than a label, a materials safety data sheet, a written training program, videotape, or a carousel of slides. Without an effective, proven means of conveying the material to workers and without feedback or evaluation loops to assure that the message is received, retained, and used, such elements are nothing more than decorative objects presented to workers in a haphazard fashion to give the illusion of communication.

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For hazard training to be effective, researchers have found that some short-term worker reinforcements and measures of effects are necessary. Cancer risk or fatal injury are just two seemingly rare and too distant in the future and too catastrophic to provide that kind of short-term training and evaluation feedback that's needed to assure effective hazard communication.

Neurotoxic symptoms, on the other hand, are daily occurrences for many workers, providing opportunities for low-cost, short-term training reinforcement evaluation, especially if regulation prohibited workers from being exposed at levels likely to cause neurotoxic effects regardless of currently set TLV's or PEL's.

Hazard training and workplace monitoring based on recognition of avoidance of neurotoxic symptoms, perhaps as part of a generic neurotoxin standard, could be one very powerful tool for minimizing workplace risk of disease and illness, especially among groups such as painters, where up to 84 percent are subject to signs and symptoms of overexposure at some time or the other.

While the use of neurotoxic symptoms as control indicator for general overexposure has been pioneered by IBPAT, more research is needed to ascertain the correlations, if any, between control of neurotoxic effects and reductions of risk from other disease-causing workplace agents.

But reason tells us that keeping exposures below levels at which neurotoxic effects occur also reduces exposure which may cause other diseases.

Today people are taking hazard communication more seriously than ever before. For example, some parents now think warning on record albums, including a full list of contents, will save kids from moral damage. The idea gets a lot of support from the Reagan administration and those ensconced in various capacities within it. So what about workers who use neurotoxins? Should we save kids from purportedly character-damaging lyrics only to destroy them and their parents with chemical exposure?

We also see a publicized crackdown on designer drugs and other substances are controlled because they cause mental effects. Don't workers deserve the same considerations when they are unknowingly exposed in occupations, gainfully employed, trying to make a living? It seems so, and hazard communication must be a right for all workers, not just those in manufacturing, as the current hazard communication standard is based.

Basing it on—artificially-based on SIC codes is inappropriate. They do not reflect when and where hazardous substances will be found and to what degree. But merely expanding the scope of coverage isn't going to make hazard communication standard work. Many other factors are necessary.

OSHA's proposed hazard communication standard does not require any evaluation of label effectiveness, yet claims to be performance oriented. Allowing manufacturers to design their own labels is fine, but it's not performance oriented when they are not required to establish a basis for the label's effectiveness.

A cursory examination of any of today's product labels will reveal how far these labels must go before they would be effective. For example, typical labels say, "Dizziness and headache may result." They do not say that if dizziness results you have been

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overexposed, nor that this overexposure can be harmful to your health. In fact, they imply dizziness is a natural side effect of use, something to be looked for. They don't even warn against driving motor vehicles or drinking alcoholic beverages after a product use, but they certainly warn you not to drink the paint. This warning is just about as helpful as "use with adequate ventilation." As one member says, "You don't know if it's adequate until you fall out on the floor."

A hazard communication standard without requirements—I should mention that the HMIS system, by the way, as currently designed, is not applicable in construction, though it could be.

A hazard communication standard without requirements that performance of the training and the labeling be evaluated for effectiveness poses just one more chance to continue economic dislocations which make it possible and profitable for employers and manufacturers to pass off onto the public the cost of occupational illness and injury which would be borne in the product cost.

Increasing joint responsibility between manufacturers and employers of users of hazardous products would help to prevent the blatant flip-flop scapegoating that now goes on with each accusing the other of failure to warn. In some cases this could help prevent those third party liability actions against manufacturers that result from an employer's failure to train product users and thus negate the need for unjust bills, such as Senate bill 44, to reduce product liability.

Both manufacturers and employers should be subject to strict legal liability for failure to warn and train effectively. Rather than introducing bills such as S. 44 to reduce manufacturing liability, someone should be creating legislation to extend liability to include employers. It's obvious that the worker compensation system doesn't work with only 6 percent of occupational health claims ever compensated and 55 percent of workers with occupational disabilities ending up on social security—that's occupational health disabilities. And strengthening liability laws would give employers and manufacturers good incentives to train and document well.

I've discussed illness associated with the paint trades, including high incidence of neurotoxic effects, the value of a generic standard for controlling neurotoxic exposures, the role that neurotoxic effects can play on hazard communication training and monitoring. I have posited a useful relationship of neurotoxins with other hazardous substances, including carcinogens, and I have outlined some of the many shortcomings of the OSHA hazard communication standard relating to training and monitoring, including the need to expand, scope, and require effectiveness of testing of warnings, and how the standard may help manufacturers and employers escape from legal liability. I've offered remedies such as expanding liability to include employers and requiring joint training responsibilities for certain classes of highly toxic substances.

All that remains is to discuss briefly other issues surrounding neurotoxic exposures. Signs and symptoms of overexposure to neurotoxins are frequently considered par for the job. They are often regarded as nonhazardous because they go away after a while.

However, neurotoxic exposures may result in permanent, irreversible damage at any time without predictability. They produce

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lower levels of alertness and effects are cumulative. Highly exposed persons may stop having symptoms after the natural defense mechanisms of the body are overcome. They think they are conditioned to the substance when, in fact, they are still being harmed.

Neurotoxins may be addictive or habituating. The symptoms are not yet regarded as serious by management nor, I think, by OSHA. Signs and symptoms and potential damage occur at or below current permissible exposure levels and, consequently, current PEL levels may leave workers unprotected.

Many researchers want to evalute neurotoxins one at a time, which will take forever if evaluation of other substances is any indication. Further, single substance evaluations do not take into account that most neurotoxins appear as mixtures.

Finally, many scientists would like to ignore the fact that a relationship between general solvents use and symptoms and disease has already been seen. Neurotoxic signs and symptoms are early warnings that a person is overexposed to neurotoxic substances. Signs and symptoms are immediate. They are often short term and reversible. A person can learn to recognize and avoid such symptoms, thereby reducing overall exposure to harmful substances.

Because many neurotoxins are also carcinogens, renal toxins, cardiotoxins, and so on, keeping exposure below the neurotoxic symptom threshold also reduces risk of kidney damage, liver damage, and cancer, et cetera.

Accepting neurotoxic symptoms as potential precursors of neurotoxic harm and of other diseases or illness certainly lowers the threshold of effect at which assumptions of material impairment or harm exist. It also raises such questions as: when is a worker impaired? If reaction time or judgment is affected, is the worker impaired? Must we microscopically see the damage before we believe that it exists, and soon we will be able to do that? Or is a mere reflection of impairment in performance of task sufficient? What will we do with threshold limit values which are not set to account for lower levels of exposures? And as our science improves and we begin to see smaller and smaller changes, physical changes, how do we respond for worker protection? Will a certain amount of mental loss or nervous system dysfunction become acceptable? We hope not, but we also know that neurotoxins and the effects they cause will, more than most issues, test how much our society demands that a worker give of life and health to maintain his or her job.

[The prepared statement of Mr. Wolford follows:]

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TESTIMONY OF RODNEY D. WOLFORD, DIRECTOR, DEPARTMENT OF HEALTH AND SAFETY, INTERNATIONAL BROTHERHOOD OF PAINTERS & ALLIED TRADES

My name is Rod Wolford, Health and Safety Director for the 180,000-member International Brotherhood of Painters and Allied Trades.

For the past nine years, I've researched, written and produced training materials for our union's members: painters, glaziers, glassworkers, floorcoverers, sign painters, sandblasters and other allied tradesworkers. In that time, I and my colleague, Marilyn Larson, have prepared a 272-page text and quiz book and 48 videotapes for training paint and allied tradesworkers in hazard recognition and control methods. Our materials are used by 125 field instructors who have delivered over 300,000 hours of training to 25,000 members in the last seven years. Much of our work has focused on painters.

In the United States, according to BLS, over 450,000 workers are employed as residential, construction, shipyard, railyard, industrial, maintenance or assembly line painters. One-hudred-twenty-thousand are our members.

Each year, these 450,000 painters use 8.6 billion pounds of coatings made up of 3.8 billion pounds of solvents, 2.6 billion pounds of pigments and 2.2 billion pounds of resin. In gallons, that translates to each worker using one gallon per hour, eight hours a day, five days a week for 40 weeks each year.

In these gallons and gallons of paint are 150 known or suspected carcinogens and a greater number of known and suspected workplace neurotoxins, cardiotoxins, haptotoxins, renal toxins and other physically and biologically active substances capable of killing or maiming workers.

Used properly, the risk posed by these products can be minimized: no exposure, no harm; no harm, no risk.

Unfortunately, there appears to be plenty of exposure and commensurate harm, exposure for which feasible controls exist and harm which therefore is unjustifiable.

Painters often work without fans or respirators in areas with solvent concentrations reaching 10 to 200 times OSHA's permissible exposure limits. Sometimes buildings explode; sometimes workers are overcome by vapors or are asphyxiated. These events you may read about in the newspapers or see on TV.

But accidents and sudden deaths are rare events and the human being a remarkable machine. So most painters just come and go in these hazardous work environments, day after day; often feeling nauseous, dizzy, fatigues, headachey or sick. In fact, Dr. Irving Selikoff in his 1975 "Investigations of Health Hazards in the

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Painting Trades," found 74 percent of all painters experienced such neurotoxic effects. For some, this process of over-exposure is repeated week after week, month after month, year after year.

The anecdotal evidence IBPAT has amassed during the past five years from several score member letters and a dozen or so videotape interviews presents a picture of acute and chronic human degradation: Workers who frequently have been led to believe that signs and symptoms of over-exposure are a natural part of being a painter; members who suddenly notice their ability to work and think is disappearing.

Often our contact with them begins when an acute exposure temporarily incapacitates or hospitalizes the painter. Sometimes it is an accelerated loss of energy or vitality. Maybe they scream at their children or spouses and experience uncontrolled rage without provocation. Sometimes they are beset with vague complaints of ill health: their kidneys hurt all the time or they can't sleep or they experience sexual dysfunction. Sometimes they black out while driving home from work. Or at night their breath smells like today's paint, and the next morning their urine smells the same. They can't remember names, dates, where they've been or what they were to buy at the store. But mostly, they stop caring, stop feeling and stop living.

Sometimes their families seek psychiatric care for them; sometimes they end up alone. Some lose their ability to work; few are ever compensated. Some encounter major mishaps or suffer acute toxic reactions which force them out of the job market. Often, they are replaced by the eighteen or nineteen year old who isn't as slow as "Old Joe"; the energetic youngster who begins the cycle again. And, others, like those before them, will end their painting careers as retirees, expecting to enjoy the golden years but instead suffering a diminished quality of life that could have been avoided through control of workplace toxic exposures. All suffer financially and emotionally; some so much that they just wish they were dead.

Not all evidence is anecdotal. Several hundred scientific papers demonstrate statistically significant relationships between some solvent-exposed occupations and diseases and illnesses, such as neurotoxin-induced dementia. In one Swedish study involving painters, a toxic encephalopathy nick-named "Chronic Painters' Syndrome" was identified among house painters. In as yet unpublished work by IBPAT, we observed a statistically significant relationship between worker-reported neurotoxic symptoms and total gallons of paint applied per year -- the greater the annual usage, the higher the symptoms reporting rate (Note: These use rates are controlled for respirator wear.).

Not surprisingly, many epidemiological studies reflect the magnitude of human suffering that anecdotal information reveals.

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For example, some studies show painters have 1.5 to 16 times greater risk of various illness or disease: cancers, respiratory ailments, skin diseases and neurological diseases, for example. The offspring of male painters also suffer more frequently than non-painter children from birth defects such as cleft palate or malignant brain tumors. And rates of spontaneous abortion are higher among workers exposed to some solvents used by painters, agricultural workers, zoologists, art teachers and nurses.

I'm sure most would agree that pain and suffering among victims of workplace neurotoxins is unjustifiable when feasible means of exposure control are not implemented due to structural barriers within the status quo which might be removed by voluntary industry or mandatory legislative actions. Some may callously question the significance of risk or add that costs and benefits must balance too, knowing full well that they and their loved ones will never be called upon to perform THAT kind of work.

Two such means of exposure control are those this subcommittee has asked me to address today: Hazard Communication and Workplace Monitoring. You also have requested our comments on effectiveness of hazard training programs on reducing worker exposure to neurotoxins and the use of low-cost technologies for monitoring workplace exposures. Hazard training and workplace monitoring are both part and parcel of effective hazard communication. HAZARD TRAINING is supposed to empower workers with the skills and information needed to minimize personal risk or injury. WORKPLACE MONITORING is a tool for researching and modifying training content and for assuring that the training, or, more broadly, the hazard communication works.

The destruction of human minds and nervous systems by workplace chemicals is not some story made up by workers to escape from their jobs or to perpetrate fraud against manufacturers, Social Security, welfare agencies or the U. S. public. The anectdotal and epidemiological work tells us that. And delaying regulatory or vountary action while searching for so-called individual "bad actor" chemical is not likely to move us any closer to minimizing the risk of those now exposed. The dismal record of substance-by-substance regulation of carcinogens tells us that. Substance-by-substance standard promulgation has worked only as a regulation-delaying tactic.

We have a chance to significantly reduce chemical exposures for a wide variety of workers just by accepting that neurotoxins may cause "temporary or permanent impairment or harm" and pose a "significant risk" which must be controlled by assuring that no worker is exposed in doses or for durations that cause signs or symptoms to be manifested. Accepting that, then neurotoxin control can play a significant part in reducing worker risks from other disease-causing agents. In other words, neurotoxic symptoms are a

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valuable signal of general over-exposure to a product.

Currently, IBPAT is analyzing workplace behavioral and attendent self-reported and clinical health status changes among painters with an emphasis on neurological signs and symptoms. This evaluation, which was designed by Marilyn Larson -- who is the study's principal investigator -- and me, has been made possible by a National Cancer Institute research grant to our union for assessing effectiveness of our training materials in reducing cancer risk. I think our study illustrates the power of using neurotoxic symptoms as a control indicator for worker exposures.

Here's how it works. Pre and post training, we compare within and between trained and non-trained painter groups the frequency of use of fans and respirators and the frequency of cleaning hands and face with solvents and the prevelance of neurotoxic signs and symptoms. If the training works; that is, if use of fans and respirators goes up, the cleaning of skin with solvents goes down and the neurotoxic signs and symptoms of over-exposure correspondingly reduce in the trained group but remain unchanged in the non-trained group, then we can conclude that the training measurably affects behaviors and health outcomes associated with lowering exposures, hence reducing risk. Now, because many neurotoxins are, or are found together with, carcinogens in paint products, this risk reductions associated with short-term effects of solvent over-exposure may serve as a proxy for lowered risk of long-term diseases, including cancers. If no corresponding changes in behavior or symptoms are found, then either the training doesn't work or its effect cannot be measured by the parameters we've designed and the effectiveness of the training remains unknown.

Such an assessment represents the "bottom line" in using "communications," such as training or labeling, as a means of reducing workplace exposures. Does the training or the label perform? Does it communicate its message? Does the message measurably change behavior? Do the measurable behavioral changes produce correspondent measurable reductions in exposure? That is, does the training or the label actually reduce risk or is it just a Machiavellian exercise to meet statutory obligations, reduce corporate liability and make undeserved profits from exploiting worker health to the long-term detriment of the public, future generations and the overall well-being of our country?

Of course, the answers to these questions cover an area of hazard communication far broader than the issue of neurotoxins.

Hazard communication is more than a label, a Material Safety Data Sheet, a written training program, videotape or a carousel of slides. These are the elements of communication and provide a pathway between the source and the receiver of the message.

But without an effective and proven means of conveying the

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materials to workers and without feedback, or evaluation loops, to assure that the message is received, retained and used, such elements are nothing more than decorative objects presented to workers in a haphazard fashion to give the illusion of communication.

In theory, training content is the message conveyed between the source (employer) and the receiver (worker) using various media, or paths, such as classrooms, workplace sessions, lectures, videotapes, labels, MSDSs. And workplace monitoring results, such as tests of knowledge or skill, industrial hygiene measurements, biological and physical measures of exposure or effects or exposure and subjective and objective worker and employer reports, are the feedback required for modifying the training program and its content and for evaluating its effectiveness. No communication program deserves the name if it is absent feedback.

For hazard training to be effective, researchers have found that some short-term worker reinforcements and measures of effect are necessary. It is also reasonable to assume that we cannot wait 20 years to find out if our training program to reduce cancer is effective. We need something tomorrow.

Cancer risk or fatal injuries are just too seemingly rare, too distant in the futre and too catastrophic to provide the kind of short-term training and evaluation feedback that's needed for assuring effective hazard communication. Industrial hygiene is generally conceded to be too expensive for routine use and, additionally, today's monitoring results may mean nothing tomorrow unless conditions of use remain identical -- which, in construction, is highly unlikely.

Neurotoxic symptoms, on the other hand, are daily occurences for many workers, providing opportunity for low cost, short-term training reinforcement and evaluation, especially if regulation prohibited workers from being exposed at levels likely to cause neurotoxic effects, regardless of currently set TLVs or PELs (below which many studies show neurotoxic effects occuring).

Hazard training and workplace monitoring based on recognition and avoidance of neurotoxic symptoms, perhaps as part of a generic neurotoxin exposure standard could be one very powerful tool for minimizing workplace risk of disease and illness, especially among groups such as painters where up to 84 percent are subject to such symptoms and signs of over-exposure.

Use of neurotoxic signs and symptoms for training and monitoring purposes can be evaluated in two ways: 1) By "subjective" questionnaires, such as the "Swedish Questionnaire 16." IBPAT has used this questionnaire, with modifications, and has found a statistically significant relationship between total unprotected gallons of paint applied each year and prevelance of

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neurotoxic symptoms; and 2) By clinical tests of reaction time, memory, sensation and so on. Such tests have been given to our members by Harvard University under a subcontract in our NCI-funded study, and some strong relationships between solvents exposures and clinical changes have been seen. Furthermore, reductions in exposure appear to be related to improvements in test performance.

While the use of neurotoxic symptoms as a control indicator for general over-exposures has been pioneered by IBPAT, more research is needed to ascertain the correlations, if any, between control of neurotoxic effects and reductions of risk from other disease-causing workplace agents. But reason tells us that keeping exposures below levels at which neurotoxic effects occur reduces exposures which may cause other diseases.

Today people are taking hazard communication more seriously than ever before.

For example, some parents now think warnings on record albums -- including a full listing of "contents," will save kids from "moral damage." The idea gets a lot of support from the Reagan Administration and those ensconced in various capacities within it. So what about workers who use neurotoxins? Should we save kids from proportedly character-damaging lyrics, only to destroy them and their parents with chemical exposures? I wonder what epidemiological evidence has been produced concerning those rock lyrics and how it compares with the overwhelming scientific documentation of occupational illness that OSHA found too weak to merit consideration in extending the Hazard Communication standard to the construction industry. We also see a publicized crack-down on "designer" drugs. And other substances are controlled because they cause mental effects. Don't workers deserve the same consideration when they are unknowingly exposed in their occupations, gainfully employed, trying to make a living?

It seems so, and Hazard Communication must be a right for all workers -- not just those in manufacturing. Manufacturing and construction are artificial classifications, based on SIC codes used by the BLS. They do not reflect when and where hazardous substances will be found and to what degree.

Hazard communication programs are especially crucial for worker protection, regardless of SIC code, whenever the employer shifts responsibility for assuring a safe and healthful workplace to employee behaviors. For example, when requiring employees to use products at rates or under conditions where temporary or permanent impairment of health may result or requiring employees to wear respirators to keep breathing air concentrations of toxic agents below the OSHA PEL.

But merely expanding the scope of coverage isn't going to make

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the Hazard Communication standard work. Many other factors are necessary.

OSHA's proposed Hazard Communication standard does not require any evaluation of labeling effectiveness, yet claims to be "performance-oriented." Allowing manufacturers to design their own labels is fine, but it's not "performance-oriented" when they are not required to establish a basis for the label's effectiveness. A cursory examination of any of today's product labels will reveal how far these labels must go before they would become effective. For example, typical labels say, "Dizziness and headaches may result." They do not say "If dizziness results, you have been over-exposed." Nor that this over-exposure can be harmful to your health. In fact, they imply dizziness is a natural side-effect of use. They don't even warn against driving motor vehicles or drinking alcoholic beverages after product use. But they certainly warn you not to drink the paint. This warning is just about as helpful as "Use with Adequate Ventilation." As one of our members says, "You don't know if it's adequate till you fall out on the floor." What would be better? How about a quantified ventilation requirement in cubic feet of fresh air right on the product label? As someone who has worked on exposure modeling for six years and reported findings to the American Industrial Hygiene Association, I can assure you that such requirements can be assigned.

There has been some slow voluntary progress on product labels. Some proposed labeling language (National Paint and Coatings Association) would say, "Do not breath vapors or mists." and "Reports have associated repeated and prolonged occupational overexposure to solvents with permanent brain and nervous system damage." But nowhere is the warning that acute neurotoxic effects such as headaches, dizziness, etc., are serious symptoms of over-exposure. In addition, this proposed language too closely associates occupational over-exposure with intentional misuse.

Without evaluation of labeling effectiveness, all that is accomplished with certainty by OSHA's Hazard Communication standard is the reduction of liability for manufacturers. Consider this comment from an NPCA member corporation: "The extent of liability imposed on companies of all sizes is horrendous and real ... The problem facing us all is that our insurance carriers will be withdrawing ... I think we may be wrong as an association to resist industry labeling which does not give us a maximum effort to protect ourselves."

I wasn't alive back in the Twenties when worker compensation laws were being passed, but I note a strong similarity between this kind of regulation and that kind of law. Today some workers are beginning to recover a small percentage of what's due them for wanton and often willful disregard of their health by some manufacturers and employers. That was happening too in the Twenties

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just before worker compensation. So compensation was passed and the result today is that no worker recovers even 50 cents on the dollar for his death or disability.

A hazard communication standard without requirements that the performance of the training and the label be evaluated for effectiveness poses the same threat and offers just one more chance to continue to economic dislocations which make it possible and profitable for employers and manufacturers to pass off onto the public the costs of occupational illness and injury which should be borne in product cost. On the OSHA hazard communication docket, IBPAT raised this issue. In the final issued standard, it was ignored. As was the necessity of including construction painters who face higher risks of disease than manufacturing workers, including workers of the paint manufacturing industry.

The manufacturer should share hazard training responsibilities whenever a product's hazards required prescribed employee conduct for its safe use. For carcinogens, for example, development and/or delivery of training by the manufacturer to the user's employees could be required when the employer of users does not have such a program.

In some cases, manufacturers already provide training for making equipment perform -- with computers and Catepillars, for example. So why not for safe use of hazardous products?

Increasing the joint responsibility between the manufacturer and the employer of users of hazardous products would help to prevent the blatant flip-flop scape-goating that now goes on, with each accusing the other of failure to warn. In some cases, this could help prevent those third party liability actions against manufacturers that result from an employer's failure to train product users, and thus negate the need for unjust bills like S.44.

Outside the scope of OSHA regulations, other factors are necessary.

Both manufacturers and employers should be subject to strict legal liability for failure to warn and train effectively. Rather than introducing bills such as S.44, to reduce manufacturing liability, someone should be creating legislation to extend liability to include employers. It's obvious that the worker compensation system doesn't work, with only 6 percent of occupational health claims ever compensated and 55 percent of workers with occupational disabilities ending up on Social Security. And strengthening liability laws would give employers and manufacturers good incentive to train and document well.

All costs associated with assuring that workers have the information and skills to perform the job in a manner that is safe

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and healthful should be borne by the employer and manufacturer. They may reflect the cost in the purchase price of the products and services which are passed along to customers, but under no circumstances should these costs be permitted to pass on to the worker or the public at large. When injury, illness or death results from failure to minimize risk and ensure a safe and healthful workplace, the worker and consumer or their agents should be able to sue employers and manufacturers to recover costs and punitive damages.

In a fair market system, profits should be drawn from the ability to produce good and services competitively, rather than from exploiting the health of workers. Consequently, the costs of running an unhealthful workplace, or one that puts more burden onto the worker than on the employer for assurance of a safe and healthful workplace, should be greater than the costs of running a healthful, controlled workplace. Hazard communication, including training, labeling and appropriate feedback machanisms, is one way to help bring into line the associated hidden costs of various processes and operations. For example, if an employer can either install a fan that reduces exposure below the permissble level or give a worker a respirator, the fan may be more likely chosen if the full cost of assuring the worker can perform the job safely with the respirator is reflected in the decision to provide the respirator instead of the fan. This is as it should be. A higher cost to the employer should be reflected by the most hazardous conditions of work. This provides an incentive to reduce costs by improving workplace health and safety.

I have discussed the illness associated with the paint trades, including high incidences of neurotoxic effects; the possibility of a generic standard for control of neurotoxic exposures; the role that neurotoxic effects can play in hazard communication, training and monitoring. I have posited a useful relationship of neurotoxins with other hazardous substances including carcinogens. And I have outlined the many shortcomings of the OSHA Hazard Communication standard, including the need to expand scope and require effectiveness testing of hazard warnings and how the standard may help manufacturers and employers escape from legal liability. I've offered remedies such as expanding liability to include employers and requiring joint training responsibilities for certain classes of highly toxic substances. All that remains is to discuss briefly other issues surrounding neurotoxic exposures.

Signs and symptoms of over-exposure to neurotoxins are frequently considered par for the job. They are often regarded as non-hazardous because they go away after a while. However, neurotoxic exposures may result in permanent irreversible damage at any time, without predictability. They produce lowered levels of alertness and effects are cumulative. Highly exposed persons may stop having symptoms after the natural defense mechanisms of the

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body are overcome. They think are conditioned to the substances when in fact they are still being harmed. Neurotoxins may be addictive or habituating.

The symptoms are not regarded as serious by management, nor, I think, by OSHA. Signs and symptoms and potential damage occur at or below current permissible exposure levels and, consequently, current limits may leave workers unprotected. Finally, many researchers want to evaluate neurotoxins one at a time, which will take forever if evaluation of other substances is any indication. Further, single substance evaluations do not take into account that most neurotoxins appear as mixtures. Finally, many scientists would like to ignore the fact that a relationship between general solvent use and symptoms and disease has already been seen.

Neurotoxic signs and symptoms are early warning signals that a person is over-exposed to a neurotoxic substance. Signs and symptoms are immediate. They are often short-term and reversible. A person can learn to recognize and avoid such symptoms, thereby reducing overall exposure to harmful substances. Because many neurotoxins are also carcinogens, renal toxins, cardiotoxins and so on, keeping exposure below the neurotoxic symptoms threshold also reduces risk of kidney damage, liver damage, cancers and so on.

However, accepting neurotoxic symptoms as potential precursors of neurotoxic harms and of other disease or illness certainly lowers the threshold of effect at which assumptions of "material impairment or harm" exist. It also raises such questions as "When is a worker impaired?" If reaction time or judgment is affected, is the worker impaired? Must we microscopically "see" the damage -- and soon we will; or is mere reflection of impairment in performance tasks sufficient? What will we do with threshold limit values which often are not set to account for low level effects? And as our science improves and we begin to see smaller and smaller changes, physical changes, how do we respond for worker protection? Will a certain amount of mental loss or nervous system dysfunction be acceptable?

We hope not, but we also know that neurotoxins and the effects they cause will -- more than most issues -- test how much our society demands that a worker give of life and health to maintain his or her job.

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Mr. VOLKMER. Thank you very much, Mr. Wolford.

I recognize the gentleman from California for questions.

Mr. PACKARD. Thank you, Mr. Chairman. I'm sorry I couldn't remain for all of the testimony of the witnesses. I had a markup in another committee.

Mr. Tyson, would you please explain the difference between hazard communication and hazard identification?

Mr. TYSON. Hazard Communication is—or excuse me, hazard identification is only one small piece of what we in OSHA know as a Hazard Communication issue. And I can really point to that distinction in drawing a distinction between OSHA's initial regulatory activity with respect to this subject and what we ultimately came out with.

In 19—I believe it was late 1979—OSHA proposed what they called the labeling standard, which would have made available on the label information with respect to a substance, but it was limited to just that information, the chemical identity and any toxic properties. We took a look at that and changed the emphasis dramatically to one of communication, because the issue, it seemed to us, was not whether or not you had the proper title on the label or whether or not the information was there, but whether or not that information was adequately communicated to the employees.

This same distinction can be drawn in many cases between the Federal Hazard Communication Standard and many State right-to-know laws which are currently being promulgated by various States, in that the State right-to-know laws often simply say that the information is there, but there is no concomitant requirement that that information be communicated and explained to employees. Our standard does that and I think, as a result, is a much stronger standard and a better approach.

Mr. PACKARD. What kind of a followup or monitoring system do you have of the communication system?

Mr. TYSON. Well, the standard goes into effect November 25 of this year for the chemical companies in this country; it goes into effect for the rest of manufacturing on May 25 of next year, some 6 months later.

When we—when it does go into effect, we will be looking at the employer—and employer's hazard communication program as a part of every inspection we do, to insure that it's being adequately carried out. We'll also be reviewing early on in the process the adequacy of the material safety data sheets themselves and the process by which chemical manufacturers go through the evaluation to make sure that proper data is put on those material safety data sheets in the first place.

Mr. PACKARD. Mr. Wolford, how many industries do you know that keep health records of its workers from the very beginning of their employment?

Mr. WOLFORD. I would suggest very few do that currently, especially in the construction industry where I'm primarily located. That's a distinction that may be important, because my primary area of expertise is in the construction industry which is distinct from manufacturing. In that regard, in construction it's very, very uncommon.

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Mr. PACKARD. Would—in your judgment, would it be advisable to require that of all industry?

Mr. WOLFORD. Well, I'm not—I would not want to suggest that all industries need to maintain a constant supply of records. I think that some of it can be done by subsampling population, selecting groups, where you may not need to keep records for all but perhaps for representative groups.

Another possibility might be to categorize in the construction, for example, means by which workers are exposed—rates of applications or processes—and then use representative samples of workers from those subsamples to base evaluation on.

I do think that, to the extent that it would be feasible, record-keeping for all industries would be advisable or would be good, but I also recognize there are some limits on feasibility, which is why I'm suggesting perhaps alternative methods.

Mr. PACKARD. Mr. Sides, I reviewed your testimony even though I didn't hear it. In your judgment do you feel that protective equipment and engineering controls are the only ways of protecting the workers?

Mr. SIDES. Well, as an industrial hygienist, there's a hierarchy of available controls, the first being engineering controls and the second administrative; that is, limiting the amount of time an employee is actually exposed to a chemical, and the third being the use of personal protective equipment. Those are the only ones that are traditionally used in the practice of industrial hygiene in our industry and in most others.

Mr. PACKARD. Is the protective equipment—is there significant improvements being made on a regular basis in protective equipment? Is the industry addressing research and development of adequate protective equipment or are we still living with basically the technology that we have known and understood for the last two decades?

Mr. SIDES. Well, I would say there is significant improvements in the protective equipment, but I think where the major improvements have come is in industry's understanding of how this equipment has to be used and maintained to be effective.

Our industry has recognized this for some years and prepared the respirator fit test training program to supply our membership with information on how to effectively use respirator protection.

In the same light, we're working on a program with the Brotherhood right now to address some of the concerns that they have about respirator usage and coming up with a fit test training program that will allow for effective use of respirators once it's been determined that that's the control mechanism that should be used.

Mr. PACKARD. Is industry generally doing all they should do to communicate to the workers the need and the guidelines, the importance of the use of protective equipment, or do you feel that there should be or could be better communication of the effective use of them?

Mr. SIDES. Again, I'd have to refer to the bulk of our testimony, which was on HMIS, and the paint industry has been using that for many years now. I think with the advent of the OSHA hazard communication standard, you'll see industry coming in line. At

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least those who are not using hazard communication systems will be bringing it into play. And the end result should be a reduction.

Mr. PACKARD. Thank you, Mr. Chairman. I don't have any further questions.

Mr. VOLKMER. I have several questions.

As I understand, Mr. Tyson, the hazard communication standard will only apply to those manufacturing, chemical manufacturing concerns that are basically on your list; is that correct?

Mr. TYSON. No, sir; that's not correct. The Hazard Communication Standard will apply to all manufacturing——

Mr. VOLKMER. What about——

Mr. TYSON [continuing]. Regardless of size, regardless of what list they're on.

Mr. VOLKMER. What about the ones—the people that receive from them?

Mr. TYSON. The issue and the issue that we are looking at right now is whether or not to cover the nonmanufacturing segment of the economy. And in Mr. Wolford's testimony, he talked about that.

That's an issue that we're moving on now.

Mr. VOLKMER. Well, let me interrupt.

Mr. TYSON. Certainly.

Mr. VOLKMER. We're not communicating. It's my fault.

Let's take a supposition. I'm a chemical manufacturer.

Mr. TYSON. Yes, sir.

Mr. VOLKMER. I receive an order from a firm that's on your Standard Industrial Classification List.

Mr. TYSON. OK. As a manufacturing entity?

Mr. VOLKMER. Right.

Mr. TYSON. OK.

Mr. VOLKMER. And the chemical manufacturer furnishes the chemical to this other manufacturer.

Mr. TYSON. Yes, sir.

Mr. VOLKMER. There has to be a communication.

Mr. TYSON. Right. There has to be a material safety data sheet that accompanies that shipment and the containers have to be labeled.

Mr. VOLKMER. Well, right. I won't get into that. At least there has to be——

Mr. TYSON. Yes, the Act would cover that situation. The standard would cover that situation.

Mr. VOLKMER. Now I am a manufacturer and I want to use that chemical and I'm not on that classification list.

Mr. TYSON. If you are a manufacturer, then you are still covered, and the standard would apply. If, however, you are in a nonmanufacturing——

Mr. VOLKMER. If I'm an end user.

Mr. TYSON. If you're an end user, not in manufacturing, then you are not covered by the standard and there is no requirement that the material safety data sheet accompany that shipment. We anticipate that it will, but it is not required right now.

Mr. VOLKMER. At the present time how much of the work force would you say that your rule, your communication rule, would cover?

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Mr. TYSON. Well, we believe that we're going to get to 70 percent of the chemical hazard injuries that have been identified by the Bureau of Labor Statistics by covering the manufacturing sector. That's where the majority far and away of the chemical injuries have been identified. So directly we will cover that area.

Indirectly, although not by mandatory regulation in the Hazard Communication as it is presently written, we expect that other than manufacturers—people in the services industries, for example—many of the painters that are not in manufacturing—will receive some benefit from the standard because we anticipate that material safety data sheets will still accompany the shipments and that the manufacturer of the product will not put a different label on the product depending on whether or not it is being shipped to another manufacturer or somebody who is not a manufacturer. So although we anticipate——

Mr. VOLKMER. You could normally accept what its contents are and let it go at that.

Mr. TYSON. He could choose to do so, and we would—well, it has to be labeled within the plant, but if it's being shipped out, if it's going to nonmanufacturing, our enforcement would look at the nonmanufacturing entity, and there is no requirement now that there be a label in that area.

Mr. VOLKMER. What about communicating to the employees who worked in the manufacturing plant itself?

Mr. TYSON. There is an absolute requirement there.

Mr. VOLKMER. All right. Now the communication standard itself and what goes into that label, who makes that determination?

Mr. TYSON. The standard is a performance standard in that we give some general guidelines with a few specifics as to what information has to be communicated. It basically is that if there are hazards associated with the substance, the label has to reflect those hazards. It doesn't say that you——

Mr. VOLKMER. Can I read you one and see if this would qualify? "Warning: flammable, vapor harmful, may cause skin irritation. Keep away from heat, sparks, and open flame. Avoid prolonged contact with skin and breathing of vapor or spray mist. Wash thoroughly after handling before eating or smoking. Close container after each use. Use only with adequate ventilation; 192S vapor harmful. Mixture contains isocyanates having air contaminant properties equivalent to 2-4-di-iso-cyanate. Cartridge type respirator. Use in accordance with the manufacturer's directions recommended with engineering and administrative controls. Burying contaminants are not possible."

Does that type of thing qualify?

Mr. TYSON. That would seem to qualify. What I don't know is whether or not, when they talk about use with adequate ventilation, then when they reflect the hazards associated with it, whether or not if there's a carcinogen hazard, that has not been reflected and should be.

Mr. VOLKMER. Well, you missed a word.

Mr. TYSON. Neurological.

Mr. VOLKMER. The word that caused the problem and which employees don't know what it means is "isocyanates."

Mr. TYSON. That's a class of chemicals.

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Mr. VOLKMER. Yes; but that's what causes a problem. But the employee doesn't know what it does.

Mr. TYSON. Yes. The isocyanates—

Mr. VOLKMER. He doesn't know what an isocyanate is.

Mr. TYSON. Yes. I would—

Mr. VOLKMER. I go out here in the hallway and these offices and ask people, "What's an isocyanate?" They won't know, will they?

Mr. TYSON. No, they won't, and I don't, either. I mean, I'm not going to say that I'm a chemical expert, either. I cannot tell you——

Mr. VOLKMER. So he goes ahead and he works around it and he finds that, even with the respirator, "Hey, I'm getting blurred vision. I'm—or my skin is irritating or what was my wife—what did she tell me to get from the store today? I can't remember."

But there's nothing in that one label that tells him if these things occur that it may be a fault from the chemicals used.

Mr. TYSON. Now, Mr. Chairman, I'm going to have to defer because I don't know whether or not that label would meet Hazard Communication requirements or not, because I don't know the substance and what studies have been done with respect to the basic substance and what the hazards that were identified as a result of those studies are.

Mr. VOLKMER. But what I'm getting at is none of those labels are going to require notification to the employee as to symptoms.

Mr. TYSON. No, they do. They do.

Mr. VOLKMER. They do?

Mr. TYSON. Yes, sir. Under Hazard Communication, we will have to indicate what kind of problems they're likely to have as a result of exposure.

Mr. VOLKMER. Or if you have these types of problems—turn it around—if you have these types of problems, they may be caused by this chemical's use.

Mr. TYSON. Yes. And, even more specifically, the material safety data sheet, which has to be available to that employee, will contain in great detail the health effects and the symptoms and, you know, based upon what studies and what those studies found, and the whole—a lot of information.

Mr. VOLKMER. That will have to be furnished to any employee who handles that type of chemical?

Mr. TYSON. Any employee in manufacturing has to have access to the material safety data sheet covering any substance they're exposed to.

Mr. VOLKMER. Is that the way you understand it, Mr. Wolford?

Mr. WOLFORD. I find it to be a little bit different than that. I would say that, for example, when you say that an employee must have access to it, that doesn't mean that they necessarily receive it. It just simply means that it has to be somewhere.

And while there may be a requirement that the person be trained or be informed that they can get it, it doesn't necessarily mean that they have received it.

And, in addition, just as you suggest, I can put together on paper a beautiful program, lay it down in front of all my workers, make them sign a document that says that they have received these documents which constitute training in hazard recognition, and by

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rights I have no idea or no real knowledge of what these people know. And I think one of the big problems—is that there's no way of assessing what the people have learned.

So you can say that the information, they have access to it, but it doesn't mean that they know anything about it.

Mr. PACKARD. Mr. Chairman, would you yield on that point?

Mr. VOLKMER. Yes, I yield.

Mr. PACKARD. Mr. Wolford, what would be a solution to that? You can't—I'm not sure that we ought to require a company to insure that employees have either implemented or have assimulated the information and the instructions that they have been given. What is your solution?

Mr. WOLFORD. Well, that may be one of the basic areas of argument, and I don't want to be an extremist in regard to the—to a stand on that issue, but it seems to me that the employer has a right to assure employees a safe and healthful workplace under the OSHA Act. And to the extent that the employer shifts that burden to the employee, by requiring the employee to engage in certain kinds of behaviors, so long as the employer is not directly acting on the workplace, that they have to bear that responsibility of assuring that the worker can carry out that responsibility under the OSHA Act. That may require additional cost and it may entail additional expense, but in that regard, then, that is what should be traded off in terms of the product against other alternatives—for example, keeping the workplace exposures below safe—or below the unsafe levels so that such training is not required.

By not requiring employers to make those tradeoffs, there are economic dislocations that occur. In other words, the employer can simply, instead of regulating an area and making the workplace safe and healthy, they can simply provide them with a training program that doesn't work and say this is going to do it. And then the general public ends up paying for it.

So what I'm saying is there has to be somewhere a balance, and that's why I say I'm not trying to be an extremist, but there needs to be a balance between the employer's obligation to assure that the employee is informed and the hazards that are present in the workplace and the methods of control that the employer has selected.

Mr. PACKARD. I thank the gentleman for yielding.

Mr. VOLKMER. What you're getting at, Mr. Wolford—there are a couple more areas in this regard. And that is that, with the hazard communication standard, is OSHA then basically abandoning the idea or thought of proposing standards as regard neurotoxins, chemicals in the workplace—workplace standards?

Mr. TYSON. No, sir, we are not, although, as we talked about in the last panel, there needs to be and I think a generic approach to the whole issue is a better approach than the substance-by-substance approach. We are, nevertheless, working quite a great deal on specific substance standards. At the present time we're working on asbestos, benzene, formaldehyde, MDA, and I could go on for a few more that are all specific substances, that I believe still warrant regulation.

But, as we talked earlier again, we'll never catch up. We need both approaches, I think, but there also has to be the realization

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that if we just go substance by substance that we're going to be constantly behind the power curve and playing catchup.

Mr. VOLKMER. Do you propose also in this area to use generic-type standards?

Mr. TYSON. With respect to hazard communication, I mean, I think that's——

Mr. VOLKMER. No, with respect to the workplace.

Mr. TYSON. With respect to neurotoxins in the workplace?

Mr. VOLKMER. Yes.

Mr. TYSON. We will take a look at that. I'm not sure that that's the approach that we want to use in terms of applying a generic thought, because if we list, say, 500 neurotoxins and say we're going to have a generic standard that applies to those, we'll have to demonstrate significant risk to each and every one of those, and we're going to end up back into the same sort of regulatory morass that we're in with the substance by substance.

The generic approach that I had in mind—and it is one akin to the one that we're using with hazard communication. We could look, for example, to a generic approach to the whole issue of medical surveillance and medical monitoring, and issues such as that, that do have a broad perspective that goes beyond just identifying either a substance or a class of substances.

Mr. VOLKMER. When do you anticipate that there will be some standards proposed for workplace hazards or neurotoxins?

Mr. TYSON. The specific neurotoxins that we are working on now, if I recall, MDA is a neurotoxin and we are going to do an advisory committee to try to generate a standard on MDA, and I would hope to have that standard out—I don't have the regulatory plan in front of me, but I think we're due to have it out in about a year and a half.

There are one or two other neurotoxins that are also in the pipeline that we're working on; 1-3-butadiene, for example. However, I could list maybe one or two more. It's not going to satisfy the Chair because, obviously, your concern is more than just the two or three that we are immediately working on.

Mr. VOLKMER. Yes, my concern is. You're right on that.

The other concern I have is that you originally—OSHA originally proposed a rule in 1981, January, for hazard identification. Shortly after, that proposal was withdrawn, and then approximately a little more than a year later you came out with the hazard communication. And according to the information I have, it emphasized communication rather than identification—more performatory in it, less specific; coverage was more limited; evaluation less extensive.

Mr. TYSON. Part of that is true. It is true that the standard that had initially been promulgated was withdrawn and a new standard was proposed—not promulgated; excuse me—and a new proposal was issued, which ultimately resulted in a final that we're talking about today.

A couple of interesting points with respect to that standard. One is that it was a labeling standard and would require all of the scientific data to be put on the label. We did not think that was the proper approach, the better approach being communication of that information with access to it where necessary, but we really didn't

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think that that kind of very specific chemical identity, with all—with the fine print that would be difficult to read kind of stuff would be the best mechanism of insuring employee safety.

Another point that I would mention is that that proposal also only covered the manufacturing sector, and that was what we ultimately determined to regulate in the standard that we did promulgate. The change in approach is, I think, an important one. And I think that the approach that we're using is one that will provide more useful information to the employee and will allow that employee access to the very specific type of information which would have been provided under the other provision if the employee feels like that information is necessary.

Mr. VOLKMER. Now the standard—communication standard, as far as the label requirement, will it say anything about exposure levels or not?

Mr. TYSON. Mr. Chairman, I do not believe that it references the specific exposure levels set by OSHA. The material safety data sheet will contain such information. It will also contain ACGIH exposure levels that are recommended in——

Mr. VOLKMER. That's the data that will be going to the employees that they can review before——

Mr. TYSON. Right.

Mr. VOLKMER [continuing]. They start using it?

Mr. TYSON. They have to have access to that information, and they have to be trained—an important point—they have to be trained on the provisions of the Hazard Communication Standard before they are exposed to the toxic substance.

Mr. VOLKMER. Let's suggest to you that perhaps amending or changing that standard, communication standard, to also, in that requirement little booklet or pamphlet, or whatever that's going to go to the employer or employee on this chemical, that on exposure levels you not only have in there the amount of exposure levels recommended by OSHA, but also the other standard that other groups have made like NIOSH or the American Council of Governmental and Industrial Hygienists in regard to that chemical.

Mr. TYSON. That information would be on the material safety data sheet. That's as sure as I can be without those in front of me at this time, but I'll be happy to check and, if I am wrong, I will so notify the committee.

Mr. VOLKMER. I'd appreciate that.

Are we going to have any generic standards for the training of the workers to deal with these hazardous chemicals?

Mr. TYSON. Well, the training——

Mr. VOLKMER. Are you going to leave it up basically to each employer to do his own thing?

Mr. TYSON. Well, the Hazard Communication Standard does have some guidelines for the training that's required. And as part of the compliance activities, when our inspector does an inspection, they will be interviewing employees to try to get some feedback on whether or not that training is effective.

Rod brings up a good point. It's difficult to determine whether or not the training is actually taking. You can measure input; you can measure the number of hours that you spend trying to tell an employee or any individual—we can talk about college students just

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as well as we can employees here—the type of information that's coming to them, but in terms of what they retain, well, educators have been trying to figure that out for years, and they haven't really come to total grips with that issue. And we're going to have a problem as well.

But we will be evaluating the effectiveness of that training program, but it has to be—and probably will always be—a great deal of subjective judgment.

Mr. VOLKMER. What teeth, let's put it that way, do we have in the regulations as far as failure of manufacturers to comply, No. 1, with that, or, No. 2, employers—you can address this in two separate answers; that was communications.

Mr. TYSON. Yes.

Mr. VOLKMER. And, No. 2, failure of employees [sic] to adequately train employees?

Mr. TYSON. Both provisions would be enforced through the penalty structure within the Act, which provides for (if the violation is a serious violation—and many of these would be serious violations—and it will depend on the specific factors) a penalty of up to $1,000 per violation. And, if that is determined to be willful violation (and we anticipate and in the directive I issued to the field I told the field to pay particular attention to this), if an employer willfully violates a provision of the Hazard Communication Standard, then that penalty can be $10,000. Quite frankly, I can't imagine that there are many employers out there, especially in the manufacturing area, that don't know that this Hazard Communication Standard is coming into effect and won't be taking steps to comply. We've been busy lately going through literally hundreds of various seminars and educational programs to get the word out that this standard is coming into effect.

Mr. VOLKMER. Now when you or I, as a manufacturer of a chemical, and I review this communication standard rule, and I really haven't done much testing about my chemical or anything; OK? Now what am I going to put on there?

Mr. TYSON. You've got two choices. You can either do that testing and evaluation. And it really—we need to make a distinction here. We don't require you to test. We require you to evaluate a test that somebody else may have done. You've got to evaluate whether or not within the scientific literature there is evidence of hazard with respect to the product that you are introducing into your workplace. You may either do that evaluation yourself or you may take advantage of your supplier's evaluation and just utilize that in the material safety data sheet and labeling as part of your own. But if you put your name on it, you're liable for it and we're going to look to you to make sure that evaluation was properly done. If you're simply using your upstream supplier's evaluation, then we will look upstream to that supplier and hold them responsible.

Mr. VOLKMER. Now I am a manufacturer and I, my staff, employees, prepare a label that goes on there, and we know that in the past there has been a history of some or our own employees in the plant having certain effects. We don't know if it's caused by that or maybe it's because they had an argument with their wife, or what have you. But there's been some suspected effects.

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Now we decide that would be adverse to our sales; we'd better not put that on there. So we're not going to put that on there. And they don't put it on there. And it goes out in the stream of manufacturing and people use it and everything else, and nobody really says anything but some of these other people are starting maybe to have some arguments with their wives also. All right? And that's basically all it's attributed to: they got up on the wrong side of the bed or they've been drinking too much, or that type of thing.

Do you review these labels?

Mr. TYSON. Yes, sir; we are. And what we'll be looking at is whether or not a valid test had been done. If you in your workplace had done what would be considered to be a scientifically valid, scientifically planned, scientifically conducted, then you're under an obligation to put that information on the label.

Now, to anticipate your follow-up question, How are we going to know whether or not you've done that? Under the Toxic Substance Control Act, if you've done that kind of a test, then you have to submit that information to TSCA to let them know. TSCA makes that information available to us and to a whole lot of other folks, which have picked it up in a number of resource centers that produce information on toxic substances and produce material safety data sheets.

We'll be cross-referencing all those. And if we find that a study had been done either in your place, workplace, or in another, that had been reported, but that you didn't take cognizance of and put on your label, then we're going to look to you and hold you responsible for not doing so.

Mr. VOLKMER. Except I just don't do any tests.

Mr. TYSON. If you don't do any tests——

Mr. VOLKMER. Nobody requires me to do any tests. There's nothing in the law. EPA—nothing.

Mr. TYSON. Then you are a chemical manufacturer——

Mr. VOLKMER. I just don't bother to do the tests.

Mr. TYSON. Well, then, you've got substances that are introduced in your workplace. The question is whether or not those substances have had tests done on them by anybody that have scientific validity. And if they have been done, you know, by someone else and are reported, and they're supposed to be reported, then you're still responsible for making sure that information is available. Whether you test or not, you have to go through the evaluation process, unless you use that upstream supplier's evaluation.

Mr. VOLKMER. Now I'm a paint manufacturer. And in my paint manufacturing I use certain chemicals from X, Y, and Z Corporation that forwards the information to me that this has neurotoxic effects.

Mr. TYSON. Yes, sir.

Mr. VOLKMER. And specifically says what and everything else. And I go ahead and I use it in my paint. And then I sell the paint in the hardware store or now at the discount store and every place else. What's on the label?

Mr. TYSON. You just hit one of the biggest problems that we face with respect to applying hazard communication to other than manufacturing, because we can control what happens with the manufacturing sector, but what do we do about the painter, for example,

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that is buying the paint through a consumer outlet, through a hardware store? We can't—you know, that's the Consumer Product Safety Commission. We can't control that right now.

We're looking for ways to try to figure out if we can by expanding the scope of the standard, but that is one of the toughest issues we're going to face, because how are we going to insure, one, that the label is adequate, when it is through the retail marketplace, and that the material safety data sheet accompanies that product as it moves through that hardware store? I have visions of racks in every hardware store in this country with material safety data sheets for every substance in that store, that anybody coming in who was also an employer would have to take advantage of and keep and make available to his or her employees. I mean, that may not be a bad solution, but it's going to represent a dramatic change in kind of how we do business.

Mr. VOLKMER. I just used that because we have some paint manufacturers here, and I thought maybe they might want to answer and talk about that. It could be other substances as well; we recognize that.

Mr. TYSON. Sure; any number of solvents or paint removers.

Mr. VOLKMER. What if it's not used just—let's say that you sell it to another person, let's take dry cleaning or something like that, where you use large amounts of it, then, and do it, and it's not really on a retail level. Will they have to be notified?

Mr. TYSON. No, not now. That's another difficult issue in the area that is often given as an example of why the Hazard Communication Standard should be expanded to include other than manufacturing, because right now there is no requirement within the dry cleaning establishment that they comply with hazard communication.

Now we anticipate that—trichloroethylene I think is the substance usually used—that it will be shipped in labeled containers and the material safety data sheets will accompany it, but that's more the result of product liability considerations than it is OSHA requirements.

But once they're there, once that material safety data sheet is in the workplace, our Access to Employee Records standard takes effect and requires that employees have access to that material safety data sheet.

Mr. PACKARD. Would the chairman yield on that?

Mr. VOLKMER. Yes, I will.

Mr. PACKARD. There is a significant void in the labor market in terms of being able to follow up or monitoring any kind of adequate system. Painters, as an example, there's probably a significant number of independent single painters that do not work for a painting contractor, that do not work for any specific organization with a list of employees, or that can post the various hazardous communication items so that when they come in and punch the time clock it's right there in front of them. These are guys that go down to the hardware store and pick up paint and go to the job. There's no way that you can monitor that kind of an employee——

Mr. TYSON. That's correct. That may not even be an employee.

Mr. PACKARD [continuing]. Under the system.

Mr. TYSON. He may not have any employees.

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Mr. PACKARD. And, yet, that person is just as subject to the hazards as anyone. The only communication that I think would be adequate under those circumstances is simply putting it on the containers that the person buys, that a painter buys.

So I can—I sense that there is a real difficulty.

Mr. Sides, do you have a comment on that?

Mr. SIDES. Yes. I think we can address the issue very clearly, and I'm glad the chairman picked a paint example for this particular case because I think we have a lot to say about this.

Recognizing that the OSHA hazard communication standard doesn't cover all employees and recognizing again, that there's a need for this type of information, I discussed it in my testimony, but the paint industry has prepared a labeling guide and we've addressed this very issue by providing specific labeling language on all of our products, both consumer and industrial, to address this particular issue.

In summary, our consumer label, particularly in the area of neurotoxicity, suggests that users open all windows and doors or use other means to ensure fresh air entry. It goes on to point out that, if you experience any of the symptoms of overexposure, such as eye watering, headaches, or dizziness, you should increase fresh air entry, wear a respirator, or leave the area.

On the industrial side, the label instructs employees to use respiratory protection unless air monitoring shows exposure levels are below applicable limits.

Finally, the label incorporates a warning that deliberately concentrating the vapors may lead to permanent injury or death.

And, again, besides warning of the hazard, it also provides the user of the product—and these are the people that are picking it up in the hardware stores and going out to do this kind of contract painting that you're talking about— it provides them with the type of information they need to control their exposure. And that's really what it's all about.

Mr. PACKARD. You have the time, Mr. Chairman.

Mr. VOLKMER. I'm holding up here one of your color cards, which I marked No. 1, by the way. And that's the one that says, "health, flammability"—are we going to see something similar to that on all paint cans? Is that what you're telling, all gallon paint cans?

Mr. SIDES. No, you're not going to see that on all gallon paint cans. We're certain—Mr. Wolford mentioned it, and we certainly considering some means of providing that information.

But you look at that right now. You think isocyanate is a funny thing to try to understand. You look at that label without knowledge of how the HMIS system works; it's not going to give you the kind of information that you need——

Mr. VOLKMER. That's correct.

Mr. SIDES [continuing]. Without the training to go along with it. And that's what we have to find a mechanism for doing.

The paint industry labeling guide, however, puts that type of consumer labeling language and labeling language that goes on industrial products to give the specific information.

In that area I'd like to defer to Mr. Doyle.

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Mr. DOYLE. We just want to stress, once again, that the HMIS and the paint industry labeling guide are complementary. One is not intended as a substitute for the other.

The HMIS was primarily developed for use within the manufcturing sector, the workplace. Now we are doing some work, and hopefully with the assistance of the Brotherhood, we may be able to expand the application of the HMIS to our finished products, but we have a lot of work to do on that.

But—so we look at it as mainly a workplace hazard communication program which is complemented by the traditional forms of labeling under the CPCS and FHSA that's reflected in our labeling guide. So those things go hand in hand in the workplace, and on the shelf of a retail store you're going to just see the consumer, the traditional consumer product label, which we hope——

Mr. VOLKMER. That will be printed on the label on the can?

Mr. DOYLE. Yes, sir. The traditional descriptive warnings.

Mr. PACKARD. Mr. Chairman—would the chairman yield again?

Mr. VOLKMER. Yes.

Mr. PACKARD. Let me be the devil's advocate for a moment. Aren't we simply spinning our wheels to a large degree on this labeling process? Again, if the consumer or the user does not pay any significant attention to it, it's an exercise in futility.

I could ask the chairman for a pack of his cigarettes, and for years we have been labeling cigarette packages, and yet—and it's hazardous to their health. And, yet, we have not seen an appreciable attention to that. And I'm wondering if we're finding or would find the same thing in the workplace.

Mr. Wolford.

Mr. WOLFORD. Hazard warnings do work, and there is quite a body of scientific information available which we used in our submission to OSHA under the hazard communication standard. One example is a situation in which people were given the opportunity for self-medication concerning a health problem, and what they did is they compared counts of bacteria in the urine of those people who received only warning labels and those people that received discussions. The people with the warning labels did extremely well, better than the people who received only verbal information from the physician. Those receiving both did even better; as a matter of fact, had approximately 98 percent compliance.

That kind of thing and many others do show that labels do work when they are provided to the people and when they are instructed in their use.

Cigarettes may be a special case in some regard.

Mr. PACKARD. Well, I think that labeling has its effect initially much more than it does after the painter gets used to seeing the label there or being aware that it's there. Then they become more complacent and less attention is given to the label, much like it was with cigarettes. When the Attorney General [sic] put it—insisted it be put on a pack of cigarettes, it did draw attention initially. Then a couple of years later it was almost as though it was not there. Complacency tends to set in, and perhaps labeling of any product would find the same situation; I don't know.

Mr. WOLFORD. I also believe, though, that we have seen reductions in numbers of people smoking cigarettes as well, and some of

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that may be attributable to labeling, simply because many of the new smokers are younger people who may not have had the same full opportunity for exposure to the labeling.

The other thing, as far as wearing out the message, that's one of the very important reasons for followup and ongoing monitoring or ongoing reinforcement. I know that's a difficult problem, but when you give someone a label, study after study has shown—or give them training—after 6 months all of that effect is gone unless there is some kind of followup reinforcements occur in a periodic fashion.

Mr. PACKARD. I think my line of comments are directed toward the idea that we ought not to put all of our faith in one single process of trying to make public awareness; that we may need a combination of many processes in an effort to try to cut back on injuries and illnesses from chemicals.

Thanks, Mr. Chairman, for yielding.

Mr. VOLKMER. Yes. Before I go any further—I meant to do this earlier—and if the paint manufacturers, coating manufacturers have no objection—I'd like to ask the reporter to go off the record just for a minute.

[Off the record.]

Mr. VOLKMER. Does the National Paint and Coating Association propose that the information system that you have here, which I think you've done well in developing, be used to comply with OSHA's proposed Hazards Communication System?

Mr. DOYLE. Yes, sir, Mr. Chairman. We have felt all along during the development of this system—and OSHA has agreed that HMIS is an effective means of communicating hazards within the workplace. We all agree with this limitation once that container leaves the workplace because nobody's going to really know what this means without the entire educational program.

Mr. VOLKMER. That's correct.

Mr. DOYLE. But it does, as a package, with the label, the educational material, the safety data sheets, the employee education and training quiz, the implementation manual—it does as an entire package comply with the requirements of the OSHA hazards communications standard.

Mr. VOLKMER. Which means that initially—let's say all this goes into effect at a certain time, and I can foresee that manufacturers will be going through the process of having training sessions for their employees in the usage of this, those that will be exposed to it, but then 6 months go by and we've had two retirements and three people have quit, and I've replaced periodically one at a time those people over a period of, say, 1 or 2 months. Now do I have a training session each time I bring one of these people in?

Mr. DOYLE. Yes, sir.

Mr. VOLKMER. For that new person you have full training sessions?

Mr. DOYLE. Yes, sir. I believe under the OSHA standard you are required, once a new employee is hired, to put him through the same training that you did originally to bring your employees into full compliance with the standard.

So in the case of retirement or death or firing, that new employee would be afforded the same training as the old one would. And

we do recommend—and I've known, because we have had a number of our member companies that have implemented HMIS long before the advent of the hazard communications standard—that they do periodically update, probably 6 months to 1 year, the training involved in HMIS because it is continually updated; the hazards of these materials do change quite a bit; it may go from a 2 to 3 based on another study or a 3 to 4; it may have new long-term chronic health effects associated with a particular chemical. So there's an ever-changing and ever-evolving training program that our members are recommended to go through, and most of them do so.

Mr. VOLKMER. Now do you agree with me, as I review your effort or your HMIS system, that it relies very heavily on protective equipment, almost exclusively on protective equipment; is that correct?

Mr. DOYLE. It relies on protective equipment to some degree, and I'll ask Steve to follow up on this comment.

We are in agreement with the priority of engineering controls first, protective equipment second. In the situations where you have a workplace where you can't have engineering controls, then, yes, the HMIS will stress personal protective equipment more than the engineering controls. But in the larger companies, in the medium-sized companies where the money is there, the sophistication is there, then, of course, the reliance should be on engineering controls. But, again, it's designed to—designed around the particular workplace situation.

If you're outside and you're spray painting some place outside the plant, you certainly couldn't have engineering controls control that situation; you'd have to have some sort of respiratory protection.

So we—HMIS stresses respiratory protection after engineering controls are not possible.

Mr. VOLKMER. So what you're saying is that they will supplement the engineering?

Mr. DOYLE. Yes, sir.

Mr. VOLKMER. Not replace it?

Mr. SIDES. Mr. Chairman, I might add that the hazard information will remain the same on the HMIS label. It will still tell the employee everything that he needs to know about the hazard of that chemical and refer him to a material safety data sheet for other information.

What may change, depending on whether the process is enclosed, whether more ventilation is used, is that designation of what type personal protective equipment he needs to wear—maybe a different type of respirator, maybe no respirator at all, if the employee has demonstrated that his engineering controls doesn't require the use of personal protective equipment. But he'll still get the same information on the inherent hazards of the chemical.

Mr. VOLKMER. Mr. Tyson, as I understand it, there is a court order at the present time to expand the scope of the standard; is that correct?

Mr. TYSON. Almost correct. Let me——

Mr. VOLKMER. I said I understand. [Laughter.]

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Mr. TYSON. The Third Circuit Court of Appeals reviewed OSHA's Hazard Communication Standard, and as a result, issued a decision which did a number of things. One, it supported the standard and said that it was okay. But it also said that OSHA's rationale for not covering nonmanufacturing was inadequate, and it directed OSHA to go back and either support its rationale better or to expand the scope.

What we are interpreting that as meaning is that we'd better go through a rulemaking to find out whether or not we should expand the scope of hazard communication to nonmanufacturing, and we have started—or will be starting very shortly—that rulemaking. I literally have the final draft of the Advance Notice of Proposed Rulemaking in my briefcase to take with me on this trip. So it's close.

Mr. VOLKMER. Well, let me ask you this: Wouldn't it be better for all concerned, rather than going through the time to justify not including——

Mr. TYSON. Oh, yes——

Mr. VOLKMER [continuing]. To go the other way and——

Mr. TYSON. Sure. Sure. I mean, that's what the proposal will be is proposing to include it.

Mr. VOLKMER. Right.

Mr. TYSON. What we want to do is—the issues we mentioned earlier with respect to some of the more difficult situations to apply hazard communication need to be better fleshed out. If you just took the regulation as it is currently written and said, "Bingo, you're now—you know, you now apply nonmanufacturing," there are areas where it just won't work. It will have trouble with the employer who obtains supplies through the retail outlet, the hardware store we talked about earlier. There are problems with construction sites with the changing workforce and the requirement for training there, and the exposure of employees other than the employees of the immediate employer to a substance that might be used there. So there are a number of issues that we need to address before we can actually accomplish that expansion of scope, but right now we are moving down the course to expand the scope of hazard communication to nonmanufacturing.

Mr. VOLKMER. Mr. Wolford, would you like to comment on that?

Mr. WOLFORD. Yes, I would. Yes, I would.

One thing, going back earlier, when hazard communication was first proposed by the current OSHA administration, the issue of construction—it was asked if it should include construction, and we submitted a lot of evidence, epidemiological evidence and other evidence, indicating that construction workers, and especially among painters, experienced very high rates of disease and illness.

In doing that, earlier—and I'm referring back to an earlier remark—Mr. Tyson said that they chose to cover the manufacturing sector because one-half of the reported injuries—or, excuse me, occupational illnesses—occurred there, even though they represent only 33 percent of the employment.

Mr. VOLKMER. Seventy percent, I believe it was that Mr. Tyson used; is that correct?

Mr. TYSON. I think that was the number.

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Mr. WOLFORD. His 70 percent is also erroneous in terms of it would eliminate 70 percent perhaps of the chemical exposures, but really it only covers 14 million people, the manufacturing sector, which is actually only about 20 percent of the workforce. So the manufacturing sector is really—when he said 70 percent, he's talking about of the chemical reported incidences.

But manufacturing workers are in fixed setting, and, therefore, the likelihood of records existing are much greater than for construction workers. It reminds me of a person who goes down the block to look under a light for a $20 they lost a mile away because the light is better. You may be able to see more clearly what you're looking for, but it doesn't mean that you're really looking at where the problems lie or where the solution lies.

And in that regard, I think that the inclusion of construction, especially among painters and others, that there is a tremendous need and a tremendous significance to the problems that exist there, more so than for manufacturing.

And you can compare—there was a mortality study that was done by the National Paint and Coatings Association on manufacturing workers. They found some elevated risks of cancer, minor in terms of what you see among painters who work in the trade. Among the other—but the comparison of the two, by and large, there's no doubt that the construction painter, workers in that environment are facing many times the risk of their manufacturing counterparts.

And in that regard, the problems associated with transferring hazard communication in those circumstances I think is an imperative.

Mr. TYSON. We're not arguing with that, Mr. Chairman. And, actually, the best example of all is that there are painters in both the manufacturing sector and in the nonmanufacturing sector, and they face exactly the same hazards and we have the anomalous situation right now where in one area they're covered and in another they're not.

Mr. VOLKMER. Mr. Wolford, yesterday we had a suggestion from one of the witnesses here from Little Rock—Dr. McMillan—that we have a—some type of health registry, national health registry, or a national clinical center to study and document the effects of neurotoxins and other chemicals on workers.

Do you have any comment on that?

Mr. WOLFORD. Well, those kinds of efforts I think are very important, the documentation. One of the things I brought up in my testimony that I think is also important, remembering the trouble we have in terms of getting people to remember labeling and keeping labeling in mind with people, the idea of following hazards—well, neurotoxic symptoms in that regard posed a mixed blessing, because when they are present you know that you are overexposed. It's a guarantee that you're overexposed.

And if workers were trained to keep exposures below those levels at which those symptoms manifested, you certainly would have a means of control. Because they are daily, you get daily reinforcement. If that were being done, then it would be possible, for example, to have daily reporting on selected groups of workers, repre-

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sentative groups of workers, rotational among workers, that could help to build such a registry as that.

And that, in turn, over the long term would help to show relationships even between levels of experience with neurotoxic effects and potential other effects like cancers 20 years down the road, if such registries exist.

So I think those kinds of things are valuable; that reporting as a means of controlling behavior in itself or instilling behavior is an important aspect of work.

We just finished in our study in—we're working on the National Cancer Institute study, as I mentioned. We had 400 workers who every week for a year completed a report giving their respirator use habits, their gallons-per-hour of paint used, and so on and so forth, from which we were able, then, to compare neurotoxic symptoms against reports.

We had about an 80-percent completion rate in one local and a 55-percent completion rate in another local, and that is just simply without employer cooperation. That's just union assisted. So it's even very likely that that kind of information can be collected and, with the repository, could make a lot of sense for analysis that the employer may not be equipped to do.

Mr. VOLKMER. OK. Thank you very much.

Anyone else wish to comment on that?

Mr. SIDES. Yes. I, again, just wanted to reaffirm, Mr. Chairman, if I might, that the labeling language that is on all of our products that contain potential neurotoxins—in this case, the category of solvents—has specific language identifying the effects of overexposure and I listed those earlier in response to questioning here. That information is out there.

To the extent that we need to support that with additional communication programs, our industry is active in pursuing that and looking for ways to more effectively disseminate that information.

I just want to go on record that that information is currently available on the label on the products, both in the consumer and the industrial sector.

Mr. DOYLE. Mr. Chairman, if I might add one other thing—I think, to address Mr. Packard's concern, with just the label portraying the hazards for the users is adequate. I think that we recognize that that's a continuing controversy that will continue to rage into the near future, 20 years, 30 years from now, and that's probably one of the reasons why we've embarked on this public education program. We recognize that stronger labeling language is needed.

We've gone forth with that labeling language, with particular respect to solvent neurotoxicity, but we also recognize that some people do not read those labels. So we're going to go out with this public education program, tell people again to read and heed those labels; also, tell them how to use particular products appropriately; also, tell them what type of respirator is needed, if in fact in that situation a respirator is needed.

So we will continue to look at our labels and also other programs that could assist in warning of the dangers associated with our products.

Mr. VOLKMER. Yes, Mr. Wolford?

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Mr. WOLFORD. I have two comments, one specific and somewhat nit-picking in regard to Mr. Sides' comment that their label warns of hazards of overexposure. They list the hazards in that proposed warning, but they do not indicate that they are signs of overexposure. They simply say that, if you have—it says, "If you experience eye watering, headaches, or dizziness, increase fresh air or wear protection equipment or leave the area." It does not say that those are signs of overexposure.

And, in addition, it doesn't—there are things like that that are missing in regard to it, though Mr. Sides did refer to them as signs of overexposure here in the hearing.

Mr. VOLKMER. Well, I agree. I think it's a matter of, again, the word "communication." Perhaps, Mr. Doyle and Mr. Sides, when these are prepared—sometimes we assume that when we say these things people recognize that that is a sign of overexposure; is that correct?

Mr. DOYLE. Yes. Mr. Chairman——

Mr. VOLKMER. But the thing is some people may not, and I've always said the best thing to do is say it rather—let it all be said rather than assume that something is going to be recognized.

Mr. DOYLE. I agree to some extent, Mr. Chairman. If I could read the entire label, put it into its correct context, and also I'd like to address the point that Mr. Wolford brought up earlier.

Our label for consumer products deals with neurotoxicity, and the warning portion of it—it says, "To avoid breathing vapors or spray mist, open windows and doors or use other means to insure fresh air entry during the application and drying. If you experience eye watering, headaches, or dizziness, increase fresh air or wear respiratory protection—NIOSH MHSATC23C or equivalent—or leave the area."

Now to address the concern that Mr. Wolford brought up in his statement—was, well, we see on a lot of paint cans and a solvent-containing products, "Use with adequate ventilation." Our label does not contain that. This statement that I just read you was a substitute for the use of the words "use with adequate ventilation."

We recognize that there are problems associated with those words, and we've made an attempt and we think it's a good statement, that it's readily recognizable; that if you experience these symptoms, then you should do one or two things basically: You open more windows and doors, put on a respirator, or in fact stop painting, stop using the product and leave the area until, you know, the side effects are discontinued.

And the same basic warning is for industrial products except it's stronger. It tells them that they must wear a respirator unless the employer himself can demonstrate that the air monitoring, the exposure levels, the vapor mist levels, are below the applicable limits, and in the case of the paint industry that would be the ACGIH TLV limits, and not necessarily the OSHA PEL, which in some respects is a bit higher.

So we do feel that that is an adequate label, and we have gone out to our membership with it, and they are now in the process of putting it on their containers.

Mr. VOLKMER. You do not see any necessity, then, nor undoubtedly the association members, the necessity of putting words to the

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effect that these symptoms or effects may be caused by the use of this paint?

Mr. DOYLE. No, I didn't mean to imply that we couldn't look at—relook at the label and maybe, if in fact there's a——

Mr. VOLKMER. I know, that may even sound elementary, because you're assuming that, if you have these things, everybody will know that they're caused by the paint; right?

Mr. DOYLE. Well, no, it doesn't sound elementary. I think you have a good point. If, in fact, there is a consensus and we find out that the message is not getting out to the consumers or the users of the paint, we'd be more than willing to take another look at that label and switch the words or add additional words that would help get the message out. We don't have any problems——

Mr. VOLKMER. Mr. Wolford?

Mr. WOLFORD. If I might add to that, part of the problem, even among the professional painter, or perhaps especially among the professional painter, is many of these workers, when asked or discussing it with them, believe that these signs and symptoms of overexposure are part of the work; that they are temporary, mean nothing, and go away. And in that regard, I can't see why the public in some sense wouldn't have a similar feeling if they experienced something like that.

In fact, there is an exhileration attached to it sometimes, and perhaps a person might even talk about it—how they got all whacked up at their next cocktail party while they're getting whacked up again, but the idea is that it does produce similar results, and so it's very possible that, without indicating that it is an overexposure, the harm may not be explicit.

One last point that I had intended to make—I said I was going to make two—was that: I think the manufacturers are doing a great job of training and that their program is really good, and we do support it and have worked with them somewhat on it. But I still have concerns about manufacturers doing this training and doing the work; then at that point, then, they may escape liabilities because they have proven their burden of warning, but the employer in the workplace, who is protected under worker compensation, does not have any similar motivation for compliance. And so, consequently, what has happened is workers, through hazard communication labeling, can be moved out of a position of gaining economic force to cause the system to change.

Manufacturers now warn well; employers, they don't give a damn. Why should they in that regard, if they only have to pay out $17 on every OSHA citation as an average—it's not even the cost of a respirator; 6 percent of occupational claims compensation. There's no incentive for the employer to change.

So all that happens is the manufacturer can do a great job, but the employer is still left in a situation where there's no economic incentive for them necessarily to go along or comply. What that can mean for the worker is just continuous of exposure with the manufacturer being removed from third party liability.

Mr. PACKARD. Mr. Chairman?

Mr. VOLKMER. Mr. Packard?

Mr. PACKARD. I don't see how you're going to get the manufacturers who spend a huge amount of money in advertising their

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products, getting people to purchase their product, to put something on the label that's going—in words that it's going to inhibit or deter people from buying their product. That's just counterproductive to them. It will be very difficult because they very meticulously evaluate every word that goes into advertising or in a label. And I think they will look very closely at what goes in that.

And nobody warned me that I would get nervous and forgetful and irritable and argue, and all these things, when I ran for Congress, and yet I have the same symptoms. [Laughter.]

Mr. WOLFORD. Might I add that you make a bit more money for your symptoms than the people who have been disabled.

Mr. PACKARD. I'm not sure that's true, but I don't know. I make a third of what I did before when I had to deal with hazardous materials.

But let me ask a question of Mr. Tyson, maybe in conclusion of our hearing, which has been a very good hearing.

Yesterday we voted on the floor on an amendment to the farm bill relative to OSHA's requirements moving into the farm industry, which I opposed, and I don't know how anyone else did, but enough that it didn't pass.

To what extent is OSHA's regulations involved in farming right now, irrespective of the actions yesterday? A significant amount of chemicals and pesticides are used in farm work. To what extent is there regulation?

Mr. TYSON. We have a special section of OSHA standards which just involves agriculture. Within that section of OSHA standards we cover such things as rollover protection for the tractors, rollover bars; the slow moving vehicle signs; there's an issue on anhydrous ammonia; and a few other safety-related standards with respect to machine guarding and things like that.

Most of the chemical problems within the farming industry are involved with the application of pesticides, which is regulated by the Environmental Protection Agency under FIFRA, the Federal Insecticide, Fungicide and Rodenticide Act, with respect to labeling requirements and some usage requirements.

Mr. PACKARD. So in my district where we raise winter tomatoes and a lot of other high-cost and very labor-intensive crops in San Diego County, when I see an illegal alien going down and wheeling some dust onto tomatoes and so forth, some wearing a mask and some not, who regulates that?

Mr. TYSON. EPA.

Mr. PACKARD. EPA.

Mr. TYSON. The application of a pesticide is EPA.

Mr. PACKARD. I have no further questions, Mr. Chairman. I want to compliment you on the hearing.

Mr. VOLKMER. Thank you very much.

I, too, want to thank all the witnesses for being here.

I'd like to conclude. We're past the quarter 'til to get done but we didn't.

And we all know that there is no such thing as a life free from all risks. People take risks every day—risks they know about and can choose to expose themselves to, as well as risks that are unavoidable merely by living in our modern society.

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But risks from neurotoxins are not the kind of risks that we should live with. They can ruin the best years of our lives, destroy our families, and deprive us of the intelligence and personality that make each of us a special person. The risks of neurotoxins are not well known, or understood, but that is not a reason to ignore them.

Today and yesterday this subcommittee heard some of the leading scientists in this field describe the numerous ways in which we may be harmed by neurotoxins. We have heard that not just individual chemicals, but drugs, food additives, fragrances, pesticides can damage our nervous system and deprive us of memory, concentration, touch, taste, and intelligence.

We have also heard how we could be testing new and existing chemicals to detect their neurotoxic effect. The methods of tests are there; the need is there; what is lacking is the will to act in this new but important area.

Two of the agencies charged with regulating neurotoxins—EPA and OSHA—have dealt with this problem, in my opinion, in an altogether too superficial a manner. Because a neurotoxin can permanently damage our nervous system, we should not wait until a known neurotoxin is also shown to be a known carcinogen before we regulate it.

We can and must act now to lessen the damage from exposure to neurotoxins. We have the data to justify lowering permissible exposure levels. We have the technologies to control exposures; we have the test procedures to predict health effects from exposure to suspected neurotoxins. We have the means to warn workers and to train them to deal with these chemicals.

We intended these hearing to serve as a first step in addressing the problem of neurotoxins. The Subcommittee on Investigations and Oversight will continue to explore this important problem, and we trust that this hearing will serve as a signal to EPA and to OSHA that we expect them to address the problem as well.

Any comment?

Mr. TYSON. No, sir. I always believe in letting the chairman have the last word.

Mr. VOLKMER. All right. Thank you very much.

The committee will be adjourned.

[Whereupon, at 12:49 p.m., the subcommittee recessed, to reconvene the following day, October 10, 1985.]

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APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST

October 23, 1985

The Honorable Harold Volkmer
Chairman, Investigations and
Oversight Subcommittee
Committee on Science and
Technology
U.S. House of Representatives
Washington, D.C. 20515

Dear Congressman Volkmer:

We commend you for your leadership in calling hearings on one of the most pressing and neglected health threats facing Americans today: chemicals that attack the brain and nerves, or neurotoxins. Although such substances surround all of us at work, in our homes, and throughout the environment, U.S. regulatory agencies have no effective policy for monitoring or controlling the hazards.

The Center for Science in the Public Interest, a nonprofit health-advocacy organization with 48,000 members, has for over five years been investigating reports of neurotoxic injuries and the regulatory neglect that underlies them. We are deeply concerned that the damage is going to continue to mount unchecked. Drawing on our findings, we would like to recommend steps that the government could take to protect the public against yet further harm from neurotoxins.

Controlling neurotoxicity will require a broad-scale national effort. As Drs. Weiss and Spencer have shown so effectively in their testimony, neurotoxic substances span every class of chemical, from pesticides, industrial compounds, and environmental pollutants to household products, medications, and cosmetics. Even certain food ingredients can interfere with brain function and behavior. Scientists have now catalogued some 800 proven or suspected neurotoxins (1). Among the 588 hazardous chemicals most commonly encountered in U.S. industry, 167 (28%) cause direct and significant brain or nerve symptoms -- compared to 115 compounds cited for risks to the lung and 59 linked to cancer (2).

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Worse still, the neurotoxins we know about today are probably only a small part of the problem. The vast majority of commercially important chemicals have never been tested for their effects on brain and nerve function. And in the absence of systematic testing, most of the dangers are likely to escape detection. For while neurotoxic substances can certainly cause devastating injuries -- including brain deterioration, paralysis, and death -- the levels of exposure most of us encounter are too low to bring on such obvious symptoms abruptly. All we may notice -- at least at first -- is insidious changes in the way we feel, think, or function. Although such changes can affect the quality of our lives profoundly and may progress ominously over time, it's often extremely tricky to track them back to any specific source.

To deal responsibly with this complex problem, the government will have to make improvements on at least four fronts. Above all, it is essential to institute neurobehavioral toxicity testing as a routine part of the premarket safety evaluation for new chemicals. There is no other expedient way to probe a wide range of potential neurotoxins for the information we need to set safe exposure limits before that public has suffered widespread impairment. Other changes vital for protecting public health include a strong infusion of funds into neurobehavioral toxicology research; significant reforms in our systems for monitoring and restricting chemicals already on the market; and a major campaign to educate health professionals about neurotoxins.

1. Routine Premarket Screening for Neurotoxicity

Sound protocols for screening the effects of chemicals on the nervous system already exist. The National Academy of Sciences (NAS) has outlined a sensible overall strategy calling for tests of learned and unlearned behavior in exposed animals, plus careful examination of their nerves for structural damage (see the appendix to Dr. McMillan's testimony). The Office of Toxic Substances of the Environmental Protection Agency (EPA) has issued a detailed set of neurobehavioral test guidelines that more than fulfill NAS's recommendations (3). Unfortunately, as EPA has testified, these guidelines have been applied to no more than a handful of hazardous substances. To correct this unproductive situation:

- EPA should require that any new chemical with structural similarity to a known neurotoxin or a large projected volume of production be tested for neurobehavioral toxicity according to the agency's guidelines. As a minimum, the guidelines that must be met should include those for evaluation of nerve structure, systematic screening of simple behaviors (sight, hearing, strength, reflex

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movements, etc.), and measurement of motor activity. Tests should be done for both short-term and life-long (chronic) exposures. Any chemical found to have neurotoxic properties in adults should be tested for its ability to cause behavioral birth defects after prenatal exposures (see Appendix A).

- The Food and Drug Administration (FDA) should apply the same criteria in screening new food additives for safety.
- Congress should amend the Food, Drug and Cosmetic Act to allow for similar testing of cosmetics.
- Finally, EPA and FDA should require both neurobehavioral toxicity and behavioral birth-defects testing for all pesticides and all drugs, respectively, since a very large proportion of these compounds are known to act by changing brain and nerve function.

2. Increased Funding for Research

Whatever progress we make against neurotoxins through premarket screening could be greatly expanded and accelerated by an increased investment in research. Investigators around the country are now working to refine and perfect current test procedures and to devise faster and cheaper new ones -- including some that may require only tiny bits of isolated tissue. Other researchers, who are studying the basic mechanisms by which neurotoxins inflict damage, can undoubtedly also steer us to better strategies for prevention. But these advances can't be realized without adequate resources. And government budget estimates show that neurobehavioral toxicology research is seriously underfunded. A greatly expanded base of support is needed:

- EPA and FDA should have much higher allocations for research on neurotoxins. Both agencies currently spend less than one-third of one percent of their operating budgets for studying these chemicals (4, 5). (See Appendix B).
- The National Institutes of Health (NIH) and the National Institute of Mental Health should also make neurotoxins a higher priority. Within this group, the branch that funds by far the greatest amount of neurobehavioral toxicology research is the National Institute of Environmental Health Sciences, which has allocated for that purpose about $8 million per year (5,6). That's an extremely modest amount that can't go far -- a mere drop in the bucket compared to the overall NIH research budget of around $4 billion (4).

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3. Improved Surveillance and Control of Chemical Already on the Market

Most of the chemicals now circulating in commerce came into use before safety assessment rules were instituted. Moreover, even chemicals that pass the premarket safety tests can sometimes cause unexpected problems after many millions of people have been exposed. As a result, safety standards often must be established or adjusted at this late stage. At present, the need for postmarket monitoring and control is especially critical for neurotoxins, since so little is done to detect the dangers earlier:

- The Occupational Safety and Health Administration (OSHA) should require industries that use substantial amounts of solvents, toxic metals, or pesticides to test for nerve impairments in their employees. Each new worker should get a baseline evaluation of nervous-system function as part of the pre-employment physical, followed by regular check-ups to reveal any slowly developing or insidious changes. As the evidence accumulates, exposure standards may have to be tightened to reflect this long-term dimension of neurotoxicity.

- In the meantime, OSHA should adopt without further delay the stiffer exposure limits that the National Institute for Occupational Safety and Health has already recommended for dozens of the most conspicuous workplace neurotoxins.

- FDA and EPA should begin to incorporate into their reviews of pre-existing drugs, food additives, pesticides, and other hazardous compounds the same neurobehavioral toxicity guidelines recommended for testing new chemicals (see section 1).

- Both FDA and EPA should also be doing a great deal more than they are now to register and follow up on the complaints of people who report adverse reactions to foods, medicines, pesticides, or consumer products.

4. Education of Health Professionals

The key to more effective monitoring of neurotoxic side effects in people is making sure that health professionals know what to look for. As it stands now, few physicians are trained to recognize the role of occupational and environmental compounds in causing illness of any kind. When the symptoms are princi-

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pally mental or behavioral, misdiagnosis is even more likely. To dispel the confusion, government should be developing a wide range of educational resources. For example:

- EPA could request and Congress fund a major National Academy of Sciences report on neurotoxicity.
- NIH could sponsor a consensus conference and accompanying report on diagnosis of neurotoxic injury.
- Both regulatory and research agencies could prepare informative pamphlets, bibliographies, and other publications for distribution to medical, nursing, pharmacy, and public-health schools and associations, as well as to occupational safety groups and labor unions.

This hearing is itself a landmark in raising public awareness of neurotoxicity. We hope it will be just the first step in a new era of enlightened government action. Thank you for allowing us the opportunity to comment on this important issue.

Sincerely,

Bambi Batts Young

Bambi Batts Young, Ph.D.
Director
Environment and Behavior
Project

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APPENDIX A

ST. LOUIS
POST-DISPATCH

Birth Defects Of The Mind

By Bambi Batts Young

Thalidomide. In 1961, doctors discovered that this drug, prescribed to pregnant women as a sleep aid, made their babies hideously deformed. Swiftly, federal regulatory officials began ordering new safety tests to detect other substances that might cause mutilating physical birth defects.

But they left a giant loophole. The most common type of birth defect in people is not misshapen bodies, but serious mental and behavioral handicaps. Yet today, more than 20 years after thalidomide, our government virtually never asks manufacturers to test whether any of their products could cause birth defects of the mind.

As a result, substances that warp prenatal brain and nerve development are seldom recognized or controlled until countless infants have been harmed. Take the case of Christine and Elizabeth Harbeson. Their mother, an epileptic, had been treated with Dilantin. At the time she started taking it, thousands of women had already given birth to babies whose mental growth had been stunted by the drug. But without federal screening for such effects, the medical community was slow to recognize the connection. No warnings of this risk appeared until 1975. By then, both Mrs. Harbeson's daughters had been born with brain damage.

Dilantin isn't the only drug or chemical that can cause prenatal brain and nerve defects. Mercury contaminants in the food supply have produced mental debility and crippling coordination problems in infants exposed before birth. Cigarette smoke inhaled by pregnant women has recently been linked to childhood attention disorders. The babies of women who've eaten PCB-contaminated Lake Michigan fish show worrisome behavioral abnormalities. Barbiturates prescribed during pregnancy can make infants frantic and restless, and may also increase their risk of later learning disabilities. Prenatal brain injuries caused by alcohol consumption now rank an ominous third among the known sources of mental retardation in America.

How many other chemical substances pose similar dangers? No one can say. So far, only a handful of the 60,000 or more commercially important chemicals have ever been tested to see if they threaten the unborn child with IQ losses, hyperactivity, emotional instability or other behavioral birth defects.

The Food and Drug Administration doesn't require manufacturers to screen for such risks before putting new food additives or medications on the market. The Environmental Protection Agency has been equally lax in approving industrial products. Not even pesticides or psychiatric drugs have to be checked for their capacity to disrupt prenatal brain function — even though these compounds are expressly designed to tamper with mind and nerves.

Failure to screen for sources of behavioral birth defects flies in the face of some of the most sobering health statistics on record. Abnormalities of the mind and nerves are by far the greatest cause of long-term disability in this country. Roughly one out of every 10 children suffers from nervous-system handicaps. Why are our regulatory agencies not making a systematic search for chemicals that might contribute to such insidious disorders? By shirking such testing, the government may well be abandoning the best prospect we have for finding preventable causes of childhood brain damage.

Several other nations — Britain, France, and Japan — already require at least limited testing of new drugs in rats or mice to identify those products most apt to provoke behavioral birth defects. The Japanese and Europeans know the differences between mice and men. But they also recognize that rodent tests are crucial for setting responsible exposure limits.

Our own government agencies have sat on the sidelines too long, claiming that behavioral tests are unreliable. But the U.S. may now be in a position to take leadership in the field at last. Scientists from around the world met recently in Cincinnati to learn the results of a massive, seven-year federal study on the value of animal tests for detecting behavioral birth defects. The findings show that properly designed behavioral tests are just as reliable as many other long-accepted methods of chemical screening.

There is now a pressing need for these conclusions to be translated into action. The ultimate goal must be routine evaluation of all new chemicals for their prenatal effects on brain and nerve function.

Such a requirement would not put an undue burden on manufacturers. Testing for behavioral birth defects should cost about $15,000 or less per compound. That isn't much when compared with the half-a-million dollars or more it usually takes to conduct other tests needed for a chemical's approval — and the lifelong cost of mental retardation and instability.

Bambi Batts Young is director of the Environment and Behavior Program at the Center for Science in the Public Interest, a nonprofit health-advocacy organization in Washington.

Feb. 23, 1983

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APPENDIX B

ESTIMATED FUNDING LEVELS FOR FEDERALLY SUPPORTED PROGRAMS

FISCAL YEAR 1983

Agency	Total Operating Budget	Budget for All Toxicology Research	Budget for Neurobehavioral Toxicology Research
	All figures are millions of dollars		
NIEHS	$164.86	$116.05	$8.23
EPA	$1,049.69	$32.36	$2.79
FDA	$362	$27.32	$0.65
NIOSH	$50	$2.53	$0.82

NIEHS = National Institute of Environmental Health Sciences
EPA = Environmental Protection Agency
FDA = Food and Drug Administration
NIOSH = National Institute for Occupational Safety and Health

Sources: OTA, 1983; NTP, 1983; Agency budget offices; Dr. Will Nusser, NIEHS extramural program director

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American
Psychological
Association

TESTIMONY OF

Leonard D. Goodstein, Ph.D.

Executive Officer

The American Psychological Association

on behalf of

THE AMERICAN PSYCHOLOGICAL ASSOCIATION

before the

U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON SCIENCE AND TECHNOLOGY

Subcommittee on Investigations and Oversight

on the subject of

Behavioral Effects of Exposure to Neurotoxins

October 8, 1985

Honorable Harold L. Volkmer, Chair

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Mr. Chairman and Members of the Committee, I am Dr. Leonard D. Goodstein, Executive Office of the American Psychological Association. I am pleased to present this testimony on behalf of the 76,000 member of APA.

The Environmental Protection Agency (EPA) estimates that there may be as many as 50,000 chemicals in everyday use, and approximately 1,000 new chemicals are introduced each year. Few of these substances are hazardous, but some are known to cause grave harm to human health. For this reason, the manufacture and distribution of certain chemicals is monitored and regulated. For the most part, these substances have been regulated on the basis of their life-threatening potential, particularly for their potential to cause cancer. As a society we are just beginning to understand that chemical substances may have serious consequences for behavior and mental health. These consequences result because chemicals have direct toxic effects on our nerve cells, or because they alter the neuro-chemical mechanisms that transmit information from one cell to another.

These hearings are a welcome sign that Congress recognizes the dangers of toxic substances to our health and behavior. We look forward to Congressional action that will reduce the damage resulting from exposure to these chemicals, and will also reduce their incidence in our environment, our homes, and our places of work.

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We come into contact with neurotoxic chemicals in many settings: In our environment, because, like lead, they are in air, the paint, and the dust of our city homes; at our place of work, if we are, for example, painters or farmers and deal with massive quantities of solvents and pesticides on a day-to-day basis; in our leisure time activities, if we are successful at catching fish which contain, unkown to us, toxic chemicals, and then we choose to eat our catch; or in our houses, in the poisons we buy to kill common household pests, the solvents we use to clean the kitchen stove, or chemical residues and additives in the foods with which we feed ourselves and our children.

The various consequences of exposure to neurotoxic substances spans the entire range of behavioral and neurological functioning. Some act mainly at the periphery of the nervous system where they are known to produce receptor or nerve cell damage leading to sensory dysfunction. Neurotoxic exposure may lead to permanent or transient impairment of hearing, of vision, of cutaneous sensibility, of taste or the sense of smell. Motor function is often affected as the exposed individual can no longer detect the subtle internal cues that are informative about position in space, or muscle strength is lost, or tremor results. Some substances act primarily on the brain. Exposed individuals can become confused and disoriented and lose their ability to remember, to comprehend the world around them, or to rationally calculate the likely consequences of their behavior. Normal social and emotional reactions can be lost, and afflicted individuals may become excessively timid and afraid of leaving the house, or touchy and overly aggressive, or they may take on the irrational behaviors and mental states or severe psychosis.

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People vary in their sensitivity to poisonous chemicals and their sensitivity may vary with their work conditions — for example, the effects of chemicals that impair hearing are more serious if the work environment is noisy. But the critical variable concerning differences in sensitivity is that for many substances the very young are the most sensitive of all. Very serious consequences of neurotoxicity can be seen in children if their mothers were exposed during the pregnancy, even though the mother may have exhibited few if any symptoms of toxicity. The child is not protected against toxic chemicals in the womb, and the developing nervous system appears to be more vulnerable to neurotoxicity than is the adult.

Another disturbing complication suggested by recent behavioral research is that although some neurotoxic effects may become less apparent as the child matures into adulthood, they can reappear as a premature loss of mental ability in the aged. These findings have enormous implications for our society. As the number of senior citizens continues to increase, we are becoming more aware of the debilitating neurological impairments that afflict many of the very old who are otherwise in good physical condition. The personal and economic costs to family and friends, and the costs to society at large, are enormous. We do not know the extent to which these neurological catastrophes result from neurotoxic exposure in the past, or will result from neurotoxic exposure in the future.

Psychologists and scientists in related disciplines have been developing sensitive measures for various aspects of sensory, motor, and mental abilities in humans over the course of the last century — measures of vision and

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hearing, for example, measure of mood and emotional behavior, measures of cognitive function and intelligence. In addition, we continue to develop animal models of many aspects of human function in each of these domains, from simple sensory and motor behaviors to emotional behavior and cognition. The development of increasingly sensitive measures for these functions -- as affected by toxic substances -- has been supported by the Environmental Protection Agency, the National Institute of Environmental Health Sciences, and the National Institute of Occupational Safety and Health. As a result of this activity, there is now very good evidence at least for some classes of chemical substances -- for example, heavy metals, solvents and pesticides -- that significant psychological consequences of toxic exposure can be demonstrated in animal models. These research results will enable us to better protect workers from neurological impairment, and protect those of us in the general population who have eaten fish or bread that have been poisoned because of the spread of neurotoxic chemicals in the environment.

The animal models for simple sensory and motor function have been shown to be valid and reliable, and they are becoming more efficient and mechanized with further refinement and the introduction of computer-controlled laboratory procedures. Regulatory agencies should take note of these developments. These agencies should include behavioral measures of central psychological functions in the guidelines for introducing new chemicals into our workplace, into our environment, and into our foods. The widespread use of these behavioral measures will add substantially to the current safeguards.

Detailed neuropsychological examinations of afflicted humans are necessary to further characterize and to understand the psychological and neurological

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consequences of their exposure to toxic chemicals. This clinical/epidemiological work should be done in conjunction with laboratory research intended to develop and exploit animal models that will simulate these effects and support their neuroanatomical analysis. The animal models will also be useful in the subsequent laboratory evaluation of suspected neurotoxins. Properly trained research personnel are required for this effort; their training should be supported by the relevant agencies.

Mental health workers must be educated to recognize and to treat the symptoms of neurotoxicity in workers and their families. Multidisciplinary programs should be instituted to increase the interactions between Graduate Departments of Psychology and Departments of Psychiatry, Neurology, and Toxicology. Clinical training funds should be available for postdoctoral work in these areas and for summer institutes and workshops that would capitalize on the combined expertise of the relevant disciplines.

We must improve methods for communicating the nature of neurotoxic hazards to workers and for monitoring health-related behaviors that are designed to reduce occupational exposure. There has been considerable psychological research done on the nature of risk-taking, how we come to understand the significance of different risks that are encountered in our everyday lives, and how we gather information and choose to change our behaviour to minimize those risks, or fail to change; this research should be applied to the problems of environmental and occupational health and worker safety. The goal of this effort is to ensure that workers understand the nature of the risks in their workplace and the ways to counter those risks, and will follow the prescribed countermeasures.

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In summary, the exposure to neurotoxic chemicals in the home, the workplace, and in the general environment is a significant health problem. Manifestations of neurotoxicity range across all behavior, from simple sensory and motor deficits, to learning disorders, and to irrational and psychotic behavior. We have these recommendations:

* Regulatory guidelines should include neurobehavioral tests in their specifications for new chemicals and in the analysis of the health effects of existing chemicals.

* More detailed neuropsychological assessment of toxicity in humans is necessary, for the greater understanding of their effects and the development of better treatments.

* Better animal models for simulating complex psychological functions must be developed, and the present models further refined. Research with animal models and human neuropsychological assessment should be coupled to their mutual benefit, and both endeavors should receive greater funding priorities. Further, researchers must be trained to ensure continued development of these sensitive measurement techniques.

* Mental health and primary care providers should be trained to recognize and to treat neurotoxic symptoms. Educational and training programs should be supported that will provide the necessary expertise.

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* Regulatory agencies should take note of recent psychological research on subjective risk assessment, risk taking behavior, and perceptual and cognitive function, and apply these findings to the communication of hazards and issues of worker compliance.

Leading psychologists and other behavioral scientists should be assembled in conference, to discuss and prescribe effective strategies to be applied to these topics. We look forward to an enlightened regulatory environment that will include neurobehavioral toxicity in its guidelines, and an increase in institutional resources in order to enable scientists and clinicians to better understand and remedy the consequences of neurotoxic exposure when it occurs.

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NEUROTOXICITY CAN BE PREVENTED

by

Raymond Singer, Ph.D

Statement presented to the United States Congress, Committee on Science and Technology, Subcommittee on Investigations and Oversights, October 20, 1985.

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WHAT IS NEUROTOXICITY?

Neurotoxicity describes the harmful effects of chemicals to the nervous system. Targets of neurotoxic chemicals include the brain, the autonomic nervous system, and the peripheral nerves (such as in the arms and legs).

WHAT CHEMICALS ARE NEUROTOXIC?

Many! Pesticides, herbicides, solvents, metals such as lead and mercury, and mixed chemical waste are all classes of chemicals which may have neurotoxic properties. The exact number of neurotoxic chemicals is endless, as commercial products with possible neurotoxic properties are synthesized daily. In a recent summary, approximately 1,000 chemicals were identified as neurotoxic. Many millions of American workers are exposed to neurotoxic chemicals on a daily basis.

WHAT ARE THE EFFECTS OF CHRONIC, LOW-LEVEL NEUROTOXICITY?

Depending upon the chemical and other factors, early effects include headache, dizziness, weakness and fatigue. Later effects include problems with memory, concentration, learning, sensory perception, personality changes, irritability, sexual and appetitive dysfunction and numbness in the arms and legs.

WHAT IS THE RELATIONSHIP BETWEEN ALZHEIMER DISEASE AND EXPOSURE TO NEUROTOXIC CHEMICALS?

We cannot say exactly at the present time. However, early symptoms of Alzheimer Disease are very similar to late effects of neurotoxicity. Although there may be a number of causes of Alzheimer Disease, one theory links Alzheimer Disease with chronic, low-level exposure to neurotoxic chemicals.

WHAT TESTS ARE USED TO DIAGNOSE NEUROTOXICITY?

Tests of central nervous system function, in current use by neuropsychologists around the country, are necessary to diagnose toxic chemical effects on the brain. Tests of peripheral nerve function are necessary to diagnose toxic chemical effects on the peripheral nerves.

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WHY IS IT IMPORTANT TO DETECT EARLY SIGNS OF NEUROTOXICITY?

Brain cells do not regenerate much, if at all. Rehabilitation of brain damage requires much time and professional resources, and may not always be effective. In the meantime, a person with chronic neurotoxicity has a miserable life. This disease robs a person of his mind and personality, leading to premature aging of the brain and the rest of the organs in the body.

CAN OCCUPATIONAL NEUROTOXICITY BE PREVENTED?

To a large extent, yes. The early symptoms and signs of neurotoxicity are detectable before extensive permanent degeneration takes place.

HOW CAN OCCUPATIONAL NEUROTOXICITY BE PREVENTED?

By monitoring workers for the early symptoms and signs of neurotoxicity.

The following industrial health program is recommended and should be required by law for industries employing workers with significant exposure to neurotoxic chemicals:

1. Before exposure, workers are screened for current neuropsychological/ neurophysiological function.

2. Workers are evaluated on a periodic basis for early signs and symptoms of neurotoxicity. Simple tests of nervous system function are administered by trained technicians.

3. Examination data is evaluated by an experienced neuropsychologist/ neurotoxicologist.

4. Workers with early neurotoxicity are counselled on ways to avoid future neurotoxicity. Those seriously affected are referred for treatment.

This program is cost-effective and is currently available.

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WHY SHOULD OCCUPATIONAL NEUROTOXICITY BE PREVENTED?

Primarily to prevent human suffering. In addition, workers with impaired brains and nerves are at increased risk of accidents. Accidents, of course, are one of the leading causes of death in this country, and incur enormous sums for treatment, lost productivity and disability benefits.

Neurotoxicity is one of the earliest signs of chemical toxicity. Cancer and other diseases take many years to develop, and have been related to the same chemicals that cause neurotoxicity. Therefore, early detection of nervous system toxicity may help stem the current epidemic of cancer.

Chronic neurotoxicity can lead to permanent brain damage, with resulting loss of worker productivity and increased costs of health and disability benefits.

Chronic neurotoxicity probably plays a significant role in the development of Alzheimer Disease in some patients. This condition affects 5-15% of the population over the age of 65. Medicaid currently pays $6.5 billion a year for nursing home care of Alzheimer patients. However, most of the costs for Alzheimer patients (currently averaging $17,000 - $50,000 per year) are borne by the victim's family.

WHEN SHOULD OCCUPATIONAL NEUROTOXICITY BE PREVENTED?

Today. The technology is available and the cost-benefit ratio is favorable to industry, workers and the American taxpayers.

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